

EXHIBIT A

1 **DALIMONTE RUEB STOLLER, LLP**

2 GREGORY RUEB, Esq. SBN 154589

3 *greg@drlawllp.com*

4 BEHRAM V. PAREKH, Esq. SBN 180361

5 *behram.parekh@drlawllp.com*

6 DALIMONTE RUEB STOLLER LLP

7 515 S. Figueroa St. Ste 1550

8 Los Angeles, CA 90071

9 T: (925) 457-8415

10 T: 619.821.2305

11 F: 855.203.2035

12 *Attorneys for Plaintiff*

ELECTRONICALLY

FILED

Superior Court of California,
County of San Francisco

12/14/2022

Clerk of the Court

BY: JEFFREY FLORES

Deputy Clerk

9 **SUPERIOR COURT OF THE STATE OF CALIFORNIA**

10 **FOR THE COUNTY OF SAN FRANCISCO**

CGC-22-603510

11 LOUISE PORRAS, an individual and on behalf
12 of the estate of EDWARD PORRAS,

13 Plaintiffs,

14 v.

15 GLAXOSMITHKLINE, LLC; BOEHRINGER
16 INGELHEIM PHARMACEUTICALS, INC;
17 BOEHRINGER INGELHEIM USA
18 CORPORATION, INC.; PFIZER, INC.; SANOFI
19 US SERVICES INC.; SANOFI-AVENTIS U.S.
20 LLC; PATHEON MANUFACTURING
21 SERVICES, LLC; WALGREEN CO.; RITE AID
22 CORPORATION; and DOES 1 through 100
inclusive,

23 Defendants.

Case No.

COMPLAINT

1. **STRICT PRODUCTS LIABILITY—
FAILURE TO WARN**
2. **STRICT PRODUCTS LIABILITY—
MANUFACTURING DEFECT**
3. **NEGLIGENCE—FAILURE TO
WARN**
4. **NEGLIGENT PRODUCT DESIGN**
5. **NEGLIGENT MANUFACTURING**
6. **NEGLIGENT
MISREPRESENTATION**
7. **WRONGFUL DEATH**
8. **SURVIVAL ACTION**

DEMAND FOR JURY TRIAL

23 **INTRODUCTION**

24 1. This is a personal injury action for damages relating to Defendants' design, manufacture,
25 sale, marketing, advertising, promotion, testing, labeling, packaging, handling, distribution,
26 transportation, and storage of ranitidine-containing drugs including the brand name, Zantac, and its
27 various generic forms ("Ranitidine-Containing Drugs," unless specifically identified).

28 2. Plaintiff brings this action for personal injuries suffered by Edward Porras as a result of

ingesting the defective and unreasonably dangerous Ranitidine-Containing Drugs and developing various cancers and their sequelae as a result of this ingestion.

3. As more particularly set forth herein, Plaintiff maintains that the Ranitidine-Containing Drugs ingested by Edward Porras are defective, dangerous to human health, unfit and unsuitable to be advertised, marketed, and sold in the United States, were manufactured improperly, and lacked proper warnings of the dangers associated with their use.

4. N-Nitrosodimethylamine (“NDMA”) is a potent carcinogen. Discovered as a biproduct in manufacturing rocket fuel in the early 1900s, today, its only use is to induce tumors in animals as part of laboratory experiments. Its only function is to cause cancer. It has no business being in a human body.

5. Zantac, the popular antacid medication that was used by millions of people every day, leads to the production of staggering amounts of NDMA when it is digested by the human body. The U.S. Food and Drug Administration's ("FDA") allowable daily limit of NDMA is 96 ng (nanograms) and yet, in a single dose of Zantac, researchers are discovering over 3 million ng.

6. These recent revelations by independent researchers have caused widespread recalls of Zantac and its generic forms both domestically and internationally, including the domestic recall by the current owner and controller of the Zantac new drug application (“NDA”). Recently, on April 1, 2020, the FDA banned all Ranitidine-Containing Drugs sold in the United States.

7. The high levels of NDMA observed in Ranitidine-Containing Drugs is a function of the ranitidine molecule: (1) the way it breaks down in the human digestive system; and (2) the way it breaks down when exposed to heat, in particular, during transport and storage.

8. This lawsuit seeks to hold Defendants responsible for defective design, manufacturing, sale, marketing, advertising, promotion, testing, labeling, packaging, handling, distribution, transportation, and storage that caused Edward Porras severe injuries.

PARTIES

I. Plaintiff

9. Plaintiff Louise Porras seeks recovery individually and on behalf of Decedent Edward Porras, who consumed Ranitidine-Containing Drugs. Decedent Edward Porras was a citizen and resident of the state of California. Decedent Edward Porras purchased and consumed Ranitidine-Containing

1 Drugs that were either, or in combination, manufactured, distributed, or sold by Patheon, a California-
2 entity with facilities in San Diego County and San Francisco County. As a direct and proximate result
3 of consuming carcinogenic Ranitidine-Containing Drugs, Edward Porras was diagnosed with Colorectal
4 Cancer. Walgreen Co. and Rite Aid Corporation supplied Edward Porras with the Ranitidine-Containing
5 Drugs which caused Edward Porras's injuries.

6 10. Based on prevailing scientific evidence, exposure to Ranitidine-Containing Drugs (and
7 the attendant NDMA) can cause cancer in humans.

8 11. Had any Defendant warned Edward Porras that Ranitidine-Containing Drugs could lead
9 to exposure to NDMA or, in turn, cancer, Edward Porras would not have taken Ranitidine-Containing
10 Drugs.

11 12. Plaintiff is informed and believe and based thereon allege that as a direct and proximate
12 result of Edward Porras use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed
13 by Defendants herein, Edward Porras suffered significant harm, conscious pain and suffering, physical
14 injury and bodily impairment including, but not limited to cancer, other permanent physical deficits,
15 permanent bodily impairment, and other sequelae. Edward Porras injuries required hospitalizations, in-
16 patient surgeries, medication treatments, and other therapies to address the adverse physical effects and
17 damage caused by Edward Porras's use of and/or exposure to Ranitidine-Containing Drugs.

18 13. As a direct and proximate result of the wrongful conduct, acts, omissions, fraudulent
19 concealments, fraudulent misrepresentations, and fraudulent business practices by Defendants and
20 DOES 1 through 100, inclusive, Edward Porras used and/or was exposed to Ranitidine-Containing Drugs
21 and was diagnosed with serious health injuries including cancer.

22 14. As a result of using and/or being exposed to Defendants' Ranitidine-Containing Drugs,
23 Edward Porras was permanently and severely injured, having suffered serious consequences from
24 Ranitidine-Containing Drugs.

25 15. As a further direct and proximate result of defects in Ranitidine-Containing Drugs and
26 the wrongful conduct, acts, omissions, and fraudulent misrepresentations of Defendants, Edward Porras
27 suffered fatal injuries.

28 16. As a further direct and proximate result of defects in Ranitidine-Containing Drugs and

1 the wrongful conduct, acts, omissions, and fraudulent misrepresentations of Defendants, Plaintiff
2 required extensive emergency medical treatment, health care, attention, and services, thereby incurring
3 medical, incidental, and service expenses pertaining to emergency medical treatments and procedures
4 undertaken in efforts to maintain and/or save Edward Porras

5 17. Edward Porras was an individual who suffered damages as a result of injuries resulting
6 from Edward Porras's use and/or exposure to Ranitidine-Containing Drugs and is authorized to bring an
7 action for the causes of actions alleged herein including, but not limited to, injuries and damages
8 sustained by Edward Porras, resulting from Edward Porras's use and/or exposure to Ranitidine-
9 Containing Drugs. Said injuries and damages sustained by Edward Porras were caused or substantially
10 contributed to by the wrongful conduct of Defendants and DOES 1 through 100, inclusive.

11 18. The product warnings for Ranitidine-Containing Drugs in effect during the time period
12 Edward Porras used and/or was exposed to Ranitidine-Containing Drugs were vague, incomplete, or
13 otherwise inadequate, both substantively and graphically, to alert consumers to the severe health risks
14 associated with Ranitidine-Containing Drugs use and/or exposure.

15 19. The Defendants and DOES 1 through 100, and each of them, inclusive, did not provide
16 adequate warnings to consumers including Edward Porras and the general public about the increased
17 risk of serious adverse events that are described herein.

18 20. Had Edward Porras been adequately warned of the potential life-threatening side effects
19 of the Defendants' and DOES 1 through 100, and each of them, inclusive, Ranitidine-Containing Drugs,
20 Edward Porras would not have purchased, used, or been exposed to Ranitidine-Containing Drugs.

21 21. By reason of the foregoing, Edward Porras developed serious and dangerous side effects
22 including cancer and other cancers, related sequelae, physical pain and suffering, mental anguish, and
23 loss of enjoyment of life. By reason of the foregoing, Plaintiff suffered economic losses and special
24 damages including, but not limited to, loss of earning and medical expenses. Plaintiff's general and
25 special damages are in excess of the jurisdictional limits of the Court.

26 22. Plaintiff has reviewed her potential legal claims and causes of action against the
27 Defendants and has intentionally chosen only to pursue claims based on state law. Any reference to any
28 federal agency, regulation or rule is stated solely as background information and does not raise a federal

1 question. Plaintiff has chosen to only pursue claims based on state law and is not making any claims
2 which raise federal questions. Accordingly, Plaintiff contends that California State jurisdiction and
3 venue is proper.

4 **II. Defendants**

5 **A. Manufacturer Defendants**

6 23. Defendant GlaxoSmithKline, LLC (“GSK”), is a Delaware limited liability company with
7 its principal place of business located at 5 Crescent Drive, Philadelphia, Pennsylvania, 19112 and Five
8 Moore Drive, Research Triangle, North Carolina, 27709. GSK is a citizen of Delaware. GSK is a wholly
9 owned subsidiary of GlaxoSmithKline, plc, which is its sole member. At all relevant times, GSK has
10 conducted business and derived substantial revenue from its manufacturing, advertising, distributing,
11 selling, and marketing of Zantac within the State of California and the counties of San Diego and San
12 Francisco.

13 24. GSK, and its predecessors, have controlled the prescription Zantac NDAs since 1983.

14 25. GlaxoSmithKline, plc¹, is a foreign entity and a citizen of the United Kingdom and is not
15 a citizen of any state in the United States. GlaxoSmithKline, plc is the successor-in-interest to the
16 companies that initially developed, patented, and commercialized the molecule known as ranitidine.
17 Ranitidine was initially developed by Allen & Hanburys Ltd., which was a subsidiary of Glaxo Labs
18 Ltd. Allen & Hanburys Ltd. was awarded Patent No. 4,128,658 by the U.S. Patent and Trademark Office
19 in December 1978, which covered the ranitidine molecule. In 1983, the FDA granted approval to Glaxo
20 Holdings, Ltd. to sell Zantac in the United States. Glaxo Holdings, Ltd. was later absorbed into Glaxo
21 Wellcome, PLC. And then, in 2000, GlaxoSmithKline, plc and GSK were created by the merger of Glaxo
22 Wellcome and SmithKline Beecham. At all relevant times, GlaxoSmithKline, plc has conducted business
23 and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing
24 of Zantac within the State of California and the counties of San Diego and San Francisco.

25 26. Defendant, Pfizer, Inc. (“Pfizer”), is a Delaware corporation with its principal place of
26 business located at 235 East 42nd Street, New York, New York 10017. Pfizer is a citizen of Delaware
27 and New York and is not a citizen of any other state. In 1993, Glaxo Wellcome, plc formed a joint

28 ¹ GlaxoSmithKline, plc is not a named defendant. GlaxoSmithKline, plc is discussed for context.

1 venture with Warner-Lambert, Inc. to develop and obtain OTC approval for Zantac. In 1995, NDA 20-
2 520 Zantac OTC 75 mg tablets were approved. In 1998, NDA 20-745 OTC Zantac 75 mg effervescent
3 tablets were approved. Also, in 1998, Warner-Lambert and Glaxo Wellcome ended their joint venture,
4 with Warner-Lambert retaining control over the OTC NDA for Zantac and the Zantac trademark in the
5 United States and Glaxo Wellcome retaining control over the Zantac trademark internationally.² In 2000,
6 Pfizer acquired Warner-Lambert and maintained control over the Zantac OTC NDA until December
7 2006. At all relevant times, Pfizer has conducted business and derived substantial revenue from its
8 manufacturing, advertising, distributing, selling, and marketing of Zantac within the State of California
9 the counties of San Diego and San Francisco.

10 27. Defendant Boehringer Ingelheim Pharmaceuticals, Inc., is a Delaware corporation with
11 its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877.
12 Boehringer Ingelheim Pharmaceuticals, Inc. is a citizen of Connecticut and Delaware, and not of any
13 other state. Boehringer Ingelheim Pharmaceuticals, Inc. is a subsidiary of the German company
14 Boehringer Ingelheim Corporation. Boehringer Ingelheim Pharmaceuticals, Inc. owned and controlled
15 the NDA for over-the-counter (“OTC”) Zantac between December 2006 and January 2017, and
16 manufactured and distributed the drug in the United States during that period. At all relevant times,
17 Boehringer Ingelheim Pharmaceuticals, Inc. has conducted business and derived substantial revenue
18 from its manufacturing, advertising, distributing, selling, and marketing of Zantac within the State of
19 California and the counties of San Diego and San Francisco.

20 28. Defendant Boehringer Ingelheim USA Corporation is a Delaware corporation with its
21 principal place of business located in at 900 Ridgebury Rd., Ridgebury, Connecticut 06877. Boehringer
22 Ingelheim USA Corporation is a citizen of Delaware and Connecticut and is not a citizen of any other
23 state. At all relevant times, Boehringer Ingelheim USA Corporation has conducted business and derived
24 substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Zantac
25 within the State of California and the counties of San Diego and San Francisco.

26 29. Collectively, Defendants Boehringer Ingelheim Pharmaceuticals, Inc. and Defendant
27

28 ² See *Warner-Lambert and Glaxo End A Venture on Ulcer Drug Zantac*, WALL STREET JOURNAL (Aug.
4, 1998), available at <https://www.wsj.com/articles/SB902188417685803000>.

Boehringer Ingelheim USA Corporation shall be referred to as “Boehringer”.

30. Defendant Sanofi US Services Inc. is a Delaware corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807, and is a wholly owned subsidiary of Sanofi S.A. Sanofi is a citizen of Delaware and New Jersey and is not a citizen of any other state. Sanofi controlled the NDA for OTC Zantac starting in January 2017 through the present and manufactured and distributed the drug in the United States during that period. Sanofi voluntarily recalled all brand name OTC Zantac on October 18, 2019. At all relevant times, Sanofi has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Zantac within the State of California and the counties of San Diego and San Francisco.

31. Defendant Sanofi-Aventis U.S. LLC was and is a Delaware limited liability company with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis U.S. LLC is a citizen of Delaware and New Jersey and is not a citizen of any other state. Sanofi-Aventis US LLC is a wholly owned subsidiary of Sanofi S.A. At all relevant times, Sanofi-Aventis U.S. LLC has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Zantac within the State of California and the counties of San Diego and San Francisco.

32. Collectively, Defendants Sanofi US Services Inc., and Sanofi-Aventis U.S. LLC, shall be referred to as “Sanofi.”

33. Defendant Patheon Manufacturing Services, LLC ("Patheon") is a limited liability company organized under the laws of Delaware. DPI Newco, LLC is the sole member of Patheon Manufacturing Services, LLC. Thermo Fisher (CN) Luxembourg Holding S.a.r.l. is the sole member of DPI Newco, LLC. Thermo CIDTEC, Inc. and TFS Life Holding, LLC are the two members of Thermo Fisher (CN) Luxembourg Holding S.a.r.l. Thermo CIDTEC, Inc. is incorporated in New York and also maintains its principal place of business in New York. TFS Life Holding, LLC has five members: (1) Thermo Fisher Scientific Life Technologies Investment UK I Limited, which is an English company; (2) Thermo Fisher Scientific Sweden Holdings, LLC; (3) Thermo Fisher Scientific Investments (Sweden) S.a.r.l.; (4) Thermo Fisher Scientific Life Investments U.S. Financing II, LLC; and (5) TFS Group Holding II, LLC. Thermo Fisher Scientific Sweden Holdings, LLC has two members, Thermo

1 Fisher Scientific Investments (Sweden) S.a.r.l. and TFS Group Holding II, LLC. Thermo Fisher
2 Scientific Investments (Sweden) S.a.r.l. has two members, CHK Holdings, Inc., a Delaware corporation
3 with its principal place of business in Massachusetts, and FSWH International Holdings, LLC. Fisher
4 Scientific Worldwide Holdings, I C.V. is the sole member of FSWH International Holdings, LLC. Fisher
5 Scientific Worldwide Holdings I C.V. has two members, Fisher Scientific Worldwide, Inc., a Delaware
6 corporation with its principal place of business in Massachusetts, and FSIR Holdings (U.S.), Inc. also a
7 Delaware corporation with its principal place of business in Massachusetts. TFS Group Holding II, LLC
8 has two members, Thermo Fisher Scientific Life Investments C.V. and TFS Group Holding I, LLC.
9 Thermo Fisher Scientific Life Investments C.V. has two members, Thermo Fisher Scientific Life
10 Investments GP, LLC and Thermo Fisher Scientific Life Holdings II C.V., Thermo Fisher Scientific Life
11 Holdings III C.V. is the sole member of Thermo Fisher Scientific Life Investments GP LLC. Thermo
12 Fisher Scientific Life Holdings III C.V. has five members: (1) Thermo Fisher Scientific AL-1, LLC; (2)
13 TFLP, LLC; (3) Thermo Fisher Scientific, Inc., a Delaware corporation with its principal place of
14 business in Massachusetts; (4) Thermo BioAnalysis, LLC; and (5) Erie Scientific, LLC. TFLP, LLC is
15 the sole member of Thermo Fisher Scientific AL-1, LLC. TFPL has five members: (1) Thermo Electron
16 Corporation, a Delaware corporation with its principal place of business in Massachusetts; (2) Erie
17 Scientific, LLC, whose sole member is Apogent Technologies, Inc., a Wisconsin corporation with its
18 principal place of business in Massachusetts; (3) Apogent Technologies, Inc.; (4) Fisher Scientific
19 Worldwide, Inc., a Delaware corporation with its principal place of business in Massachusetts; and (5)
20 Fisher WWD Holding, LLC, whose sole member is Fisher Scientific Worldwide, Inc., a Delaware
21 corporation with its principal place of business in Massachusetts. Thermo BioAnalysis, LLC has three
22 members: (1) Thermo Fisher Scientific, Inc.; (2) Life Sciences International Limited, an English
23 company; and (3) Life Sciences International, LLC, whose sole member is Helmet Securities Limited,
24 an English company. TFS Group Holding I, LLC has twelve members: (1) Thermo Fisher Scientific,
25 Inc.; (2) Thermo Luxembourg Holding, LLC (Thermo Luxembourg Holding S.a.r.l.), whose sole
26 member is Thermo Fisher Scientific Germany BV & Co. KG, which is owned by Thermo Fisher
27 Scientific, Inc. and Thermo Fisher Scientific Germany B.V., a Dutch company; (3) Molecular
28 Bioproducts, Inc., a California corporation with its principal place of business also in California; (4)

1 Thermo Fisher Scientific Investments (Sweden) S.a.r.l., which has two members, CHK Holdings, Inc.,
2 a Delaware corporation with its principal place of business in Massachusetts, and FSWH International
3 Holdings, LLC, whose sole member is Fisher Scientific Worldwide Holdings I, C.V., whose members
4 are Fisher Scientific Worldwide, Inc., a Delaware corporation with its principal place of business in
5 Massachusetts, and FSIR Holdings (U.S.), Inc., a Delaware corporation with its principal place of
6 business in Massachusetts; (5) Fisher Scientific Worldwide Holdings I C.V.; (6) Thermo Fisher
7 Scientific Life Investments U.S. Financing I, LLC, whose members are FSIR Holdings (U.S.), Inc. and
8 FSWH International Holdings, LLC; (7) Fisher Scientific Worldwide, Inc.; (8) Fisher Clinical Services,
9 Inc., a Pennsylvania corporation with its principal place of business also in Pennsylvania; (9) Liberty
10 Lane Investment, LLC, whose sole member is FSIR Holdings (U.S.), Inc; (10) Fisher Scientific
11 International, LLC, whose sole member is Thermo Fisher Scientific, Inc; (11) Thermo Fisher Scientific
12 Life Investments U.S. Financing II, LLC, whose members are Perbio Science Sweden Holdings AB, a
13 Swedish Company, and Thermo Fisher Scientific Life Investments II S.a.r.l., which is owned by Perbio
14 Science AB, a Swedish company; and (12) Erie LP Holding, LLC, whose sole member is Erie UK
15 Holding Company, a Delaware corporation with its principal place of business in Massachusetts.
16 Consequently, Patheon Manufacturing Services, LLC is a citizen of Pennsylvania. Further, Patheon was,
17 at times, engaged in the manufacture, distribution, labeling, packaging, handling, storage, transport
18 and/or selling of OTC Zantac on behalf of Defendants Pfizer, BI and Sanofi from 1995 until it was
19 withdrawn from the market due to unsafe levels of NDMA found in products. Patheon Manufacturing
20 Services is a citizen of Delaware, New York, California, Massachusetts, Wisconsin, and Pennsylvania.

21 **B. Retailer Defendant**

22 34. Defendant Walgreen Co. (“Walgreen”) is an Illinois corporation with its principal place
23 of business located at 200 Wilmot Road, Deerfield, IL 60015. At all relevant times, Walgreen Co. has
24 conducted business and derived substantial revenue from its selling of Ranitidine-Containing Drugs
25 within the State of California and Los Angeles County by operating a pharmacy which dispenses
26 Ranitidine-Containing Drugs.

27 35. Defendant Rite Aid Corporation (“Rite Aid”) is a Delaware corporation with its principal
28 place of business located at 30 Hunter Lane, Camp Hill, Pennsylvania 17011. Rite Aid is a citizen of

1 Delaware and Pennsylvania. At all relevant times, Rite Aid Corporation has conducted business and
2 derived substantial revenue from its selling of Ranitidine-Containing Drugs within the State of California
3 and Los Angeles County by operating a pharmacy which dispenses Ranitidine-Containing Drugs.

4 **C. Doe Defendants**

5 36. The true names and/or capacities, whether individual, corporate, partnership, associate,
6 governmental, or otherwise, of Defendants DOES 1 through 100, inclusive, and each of them, are
7 unknown to Plaintiff at this time, who therefore sues said Defendants by such fictitious names. Plaintiff
8 is informed and believes, and thereon alleges, that each Defendant designated herein as a DOE caused
9 injuries and damages proximately thereby to Edward Porras as hereinafter alleged; and that each DOE
10 Defendant is liable to the Plaintiff for the acts and omissions alleged herein below, and the resulting
11 injuries to Edward Porras, and damages sustained by Plaintiff. Plaintiff will amend this Complaint to
12 allege the true names and capacities of said DOE Defendants when that same is ascertained.

13 37. Plaintiff is informed and believes, and thereon allege, that at all times herein mentioned,
14 each of the Defendants and each of the DOE Defendants was the agent, servant, employee and/or joint
15 venturer of, and/or retailer or distributor for, the other co-Defendants and other DOE Defendants, and
16 each of them, and at all said times, each Defendants and each DOE Defendant was acting in the full
17 course, scope and authority of said agency, service, employment and/or joint venture.

18 38. Plaintiff is informed and believes and alleges that at all times mentioned herein,
19 Defendants and DOES 1 through 100, inclusive, and each of them, were also known as, formerly known
20 as and/or were the successors and/or predecessors in interest/business/product line/or a portion thereof,
21 assigns, a parent, a subsidiary (wholly or partially owned by, or the whole or partial owner), affiliate,
22 partner, co-venturer, merged company, alter egos, agents, equitable trustees and/or fiduciaries of and/or
23 were members in an entity or entities engaged in the funding, researching, studying, manufacturing,
24 fabricating, designing, developing, labeling, assembling, distributing, supplying, leasing, buying,
25 offering for sale, selling, inspecting, servicing, contracting others for marketing, warranting, rebranding,
26 manufacturing for others, packaging, transportation, storage, and advertising of Ranitidine-Containing
27 Drugs. Defendants and DOES 1 through 100, inclusive, and each of them, are liable for the acts,
28 omissions and tortious conduct of its successors and/or predecessors in interest/business/product line/or

1 a portion thereof, assigns, parent, subsidiary, affiliate, partner, co-venturer, merged company, alter ego,
2 agent, equitable trustee, fiduciary and/or its alternate entities in that Defendants and DOES 1 through
3 100, inclusive, and each of them, enjoy the goodwill originally attached to each such alternate entity,
4 acquired the assets or product line (or portion thereof), and in that there has been a virtual destruction of
5 Plaintiff's remedy against each such alternate entity, and that each such Defendants has the ability to
6 assume the risk spreading role of each such alternate entity.

7 39. Plaintiff is informed and believes, and thereon alleges, that at all times herein mentioned,
8 that Defendants and DOES 1 through 100, inclusive, and each of them, were and are corporations
9 organized and existing under the laws of the State of California or the laws of some state or foreign
10 jurisdiction; that each of the said Defendants and DOE Defendants were and are authorized to do and
11 are doing business in the States of California and regularly conducted business in these States and in the
12 counties of San Diego and San Francisco.

13 40. Upon information and belief, at relevant times, Defendants and DOES 1 through 100, and
14 each of them, inclusive, were engaged in the business of researching, developing, designing, licensing,
15 manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce and into the
16 State of California, including in the counties of San Diego and San Francisco., either directly or indirectly
17 through third parties or related entities, Ranitidine-Containing Drugs.

18 41. At relevant times, Defendants and DOES 1 through 100, inclusive, and each of them,
19 conducted regular and sustained business and engaged in substantial commerce and business activity in
20 the State of California, which included but was not limited to selling, marketing, and distributing
21 Ranitidine-Containing Drugs in the State of California and the counties of San Diego and San Francisco.

22 42. At all relevant times, Defendants and DOES 1 through 100, inclusive, and each of them,
23 expected or should have expected that their acts would have consequences within the United States of
24 America including the State of California and including the counties of San Diego and San Francisco.,
25 said Defendants derived and derive substantial revenue therefrom.

26 **JURISDICTION AND VENUE**

27 43. This Court has jurisdiction over this action pursuant to the California Constitution Article
28 VI, Section 10, which grants the Superior Court "original jurisdiction in all causes except those given by

1 statute to other trial courts.” The Statutes under which this action is brought do not specify any other
2 basis for jurisdiction.

3 44. This Court has personal jurisdiction over each Defendant insofar as each Defendant is
4 authorized and licensed to conduct business in the State of California, a resident of the State of California,
5 maintains and carries on systematic and continuous contacts in the State of California, regularly transacts
6 business within the State of California, and regularly avails itself of the benefits of the State of California.

7 45. Additionally, Defendants caused tortious injury by acts and omissions in this judicial
8 jurisdiction and caused tortious injury in this jurisdiction by acts and omissions outside this jurisdiction
9 while regularly doing and soliciting business, engaging in a persistent course of conduct, and deriving
10 substantial revenue from goods used or consumed and services rendered in this jurisdiction.

11 46. Plaintiff seeks relief that is within the jurisdictional limits of the Court.

12 **FACTUAL ALLEGATIONS**

13 **I. Regulatory History of Ranitidine-Containing Products**

14 47. Defendants marketed and sold Ranitidine-Containing Drugs under the brand name
15 “Zantac” or its generic version by either prescription or OTC. Defendants sold Ranitidine-Containing
16 Drugs in the following forms: injection, syrup, and/or tablets and capsules.

17 48. Zantac (ranitidine) was originally discovered and developed by scientist John Bradshaw
18 on behalf of GSK³ in 1976.

19 49. The drug belongs to a class of medications called histamine H₂-receptor antagonists (or
20 H₂ blockers), which decrease the amount of acid produced by cells in the lining of the stomach. Other
21 drugs within this class include cimetidine (Tagamet), famotidine (Pepcid), and nizatidine (Tazac).

22 50. Cimetidine (Tagamet), discovered and developed by Smith, Kline and French⁴, was the
23 first H₂ blocker to be developed and is the prototypical histamine H₂ receptor antagonist from which the
24 later members of the class were developed. Indeed, Zantac was specifically developed by GSK in
25

26 ³ Dr. Bradshaw was working for Glaxo Inc. at the time. Glaxo Inc. later merged with the Wellcome
27 Foundation in 1995 to become Glaxo Wellcome plc. Then, in 2000, Glaxo Wellcome plc merged with
Smithkline Beecham plc to form GlaxoSmithKline plc.

28 ⁴ Smith, Kline and French later merged with the Beecham Group in 1989 to form SmithKline Beecham
plc. And, as discussed above, SmithKline Beecham plc was merged into GSK in 2000.

1 response to the success of cimetidine.

2 51. Zantac was approved by the FDA, pursuant to the New Drug Application (“NDA”)
3 process in 1983 (NDA 18-703) and, quickly, became one of GSK’s most successful products, being the
4 first prescription drug in history to reach \$1 billion in sales, which in the pharmaceutical industry is
5 referred to as a “Blockbuster.”

6 52. In 1993, GSK entered into a joint venture with Pfizer⁵ to develop an OTC version of
7 Zantac. That joint venture led to FDA approval of an OTC version of Zantac in 1995. Zantac OTC was
8 approved through an NDA process (NDA 20-520).

9 53. In 1997, GSK’s patent on ranitidine expired, and generic Ranitidine-Containing Drugs
10 entered the market. Despite generic entry, however, brand name prescription and OTC Zantac continued
11 to be sold. Although sales of brand-name Zantac declined as a result of generic and alternative products,
12 Ranitidine-Containing Drug sales remained strong over time. As recently as 2018, Zantac was one of the
13 top 10 antacid tablet brands in the United States, with sales of Zantac 150 totaling \$128.9 million—a
14 3.1% increase from the previous year.

15 54. In 1998, the joint venture between GSK and Pfizer dissolved. As part of the separation,
16 GSK retained the rights to sell all forms of Zantac internationally and prescription Zantac in the U.S.,
17 while Pfizer retained the rights to sell OTC Zantac domestically and retained ownership over the Zantac
18 trademark. Under this agreement, GSK retained control and responsibility over the prescription Zantac
19 NDA and Pfizer retained control and responsibility over the OTC Zantac NDA.

20 55. In October 2000, Pfizer obtained full rights to OTC Zantac in the United States and
21 Canada from GSK pursuant to a divestiture and transfer agreement. As part of this agreement, GSK
22 divested all domestic Zantac OTC assets to Pfizer including all trademark rights and removed the
23 restrictions on Pfizer’s ability to seek product line extensions or the approval for higher doses of OTC
24 Zantac. GSK retained the right to exclusive use of the Zantac name for any prescription ranitidine-
25 containing product in the US.

27 ⁵ The joint venture was between Glaxo Wellcome plc and Warner-Lambert, Inc. Warner-Lambert was
28 later acquired by Pfizer, Inc. in 2000. For the purposes of this Complaint, Warner-Lambert will be
referred to as Pfizer.

1 56. In October 2003, Pfizer submitted NDA 21-698 for approval to market OTC Zantac 150
2 mg. The FDA approved NDA 21-698 OTC Zantac 150 mg on August 31, 2004.

3 57. In 2006, Pfizer through a divestiture agreement, transferred all assets pertaining to its
4 Zantac OTC line of products, including the rights to sell and market all formulations of OTC Zantac in
5 the United States and Canada, as well as all intellectual property, research and development, and
6 customer and supply contracts to Boehringer Ingelheim Pharmaceuticals, Inc. As part of this deal,
7 Boehringer obtained control and responsibility over all of the Zantac OTC NDAs.

8 58. In 2009, GSK ceased marketing prescription Zantac in the U.S. and abandoned the Zantac
9 prescription NDA. Although, according to GSK's recent annual report (2019), GSK claims to have
10 "discontinued making and selling prescription Zantac tablets in 2017 ... in the U.S."⁶

11 59. In 2016, Boehringer sold the rights of OTC Zantac to Sanofi US Services, Inc. As part of
12 this deal, Sanofi obtained control and responsibility over the OTC NDA and currently retains that control
13 and responsibility.

14 60. To date, the FDA has approved numerous generic manufacturers for the sale of
15 prescription and OTC Ranitidine-Containing Drugs through an Abbreviated New Drug Application
16 ("ANDA") process.

17 **II. Recalls and the FDA's Ban**

18 61. On September 9, 2019, pharmacy and testing laboratory Valisure LLC and ValisureRX
19 LLC (collectively, "Valisure") filed a Citizen Petition calling for the recall of all ranitidine-containing
20 products due to exceedingly high levels of NDMA found in ranitidine pills. FDA and European
21 regulators started reviewing the safety of ranitidine with specific focus on the presence of NDMA.⁷ This
22 triggered a cascade of recalls by the makers and retailers of Ranitidine-Containing Drugs.

23 62. On September 13, 2019, the FDA's Director for Drug Evaluation and Research, Dr. Janet
24 Woodcock, issued a statement that some ranitidine medicines may contain NDMA.

26 ⁶ GlaxoSmithKline, plc, *Annual Report* at 37 (2019), available at
27 <https://www.gsk.com/media/5894/annual-report.pdf>

28 ⁷ [https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-](https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine)
[zantac-ranitidine;](https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine) [https://www.ema.europa.eu/en/news/ema-review-ranitidine-medicines-following-](https://www.ema.europa.eu/en/news/ema-review-ranitidine-medicines-following-detection-ndma)
[detection-ndma.](https://www.ema.europa.eu/en/news/ema-review-ranitidine-medicines-following-detection-ndma)

63. On September 24, 2019, generic manufacturer Sandoz Inc. voluntarily recalled all of its ranitidine-containing products due to concerns of a “nitrosamine impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled medicine.”⁸

64. On September 26, 2019, Walgreens, Walmart, and Rite-Aid and Apotex Corp.— makers of generic OTC ranitidine—voluntarily recalled all ranitidine-containing products and removed the products from the shelves.⁹ Apotex issued a statement, noting that “Apotex has learned from the U.S. Food and Drug Administration and other Global regulators that some ranitidine medicines including brand and generic formulations of ranitidine regardless of the manufacturer, contain a nitrosamine impurity called N-nitrosodimethylamine (NDMA)[.]”¹⁰

65. On September 28, 2019, CVS Health Corp. stated that it would stop selling Zantac and its own generic ranitidine-containing products out of concern that it might contain a carcinogen.

66. On October 2, 2019, the FDA ordered testing on Zantac and specified a protocol to be used that did not involve the use of heat.¹¹

67. On October 8, 2019, GSK voluntarily recalled all Zantac and ranitidine-containing products internationally.¹² As part of the recall, GSK publicly acknowledged that unacceptable levels of NDMA were discovered in Zantac and noted that “GSK is continuing with investigations into the potential source of the NDMA.”¹³

68. On October 23, 2019, Dr. Reddy’s Laboratories Ltd and Sanofi voluntarily recalled all of their ranitidine-containing products.¹⁴

⁸ <https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-sandoz-ranitidine-capsules-following-detection-impurity>.

⁹ <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine>.

¹⁰ <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/apotex-corp-issues-voluntary-nationwide-recall-ranitidine-tablets-75mg-and-150mg-all-pack-sizes-and>.

¹¹ <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine>

¹² <https://www.gov.uk/government/news/zantac-mhra-drug-alert-issued-as-glaxosmithkline-recalls-all-unexpired-stock>

¹³ Justin George Varghese, *GSK recalls popular heartburn drug Zantac globally after cancer scare*, Reuters (Oct. 8, 2019), available at <https://www.reuters.com/article/us-gsk-heartburn-zantac/gsk-recalls-popular-heartburn-drug-zantac-globally-after-cancer-scare-idUSKBN1WN1SL>.

¹⁴ <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine>.

1 69. On October 28, 2019, Perrigo Company plc, Novitium Pharma LLC, and Lannet
2 Company Inc., voluntarily recalled all their ranitidine-containing products from the market.¹⁵

3 70. On November 1, 2019, the FDA announced the results of recent testing, finding
4 “unacceptable levels” of NDMA in ranitidine-containing products, and requested that drug makers begin
5 to voluntarily recall their ranitidine-containing products.¹⁶

6 71. Between November 1, 2019 and February 27, 2020, the following ranitidine makers
7 recalled their products from the market, citing NDMA concerns: Aurobindo Pharma USA, Amneal
8 Pharmaceuticals, LLC, American Health Packaging, Golden State Medical Supply, Precision Dose Inc.,
9 Glenmark Pharmaceutical Inc., Appco Pharma LLC, and Northwind Pharmaceuticals.¹⁷

10 72. On January 2, 2020, research laboratory, Emery Pharma, submitted a Citizen Petition to
11 the FDA, showing that NDMA accumulates in ranitidine at unsafe rates when exposed to heat levels that
12 would occur during transport and storage.

13 73. Emery’s Citizen Petition outlined its substantial concern that Ranitidine is a time- and
14 temperature-sensitive pharmaceutical product that develops a known carcinogen, NDMA, when exposed
15 to heat, a common occurrence during shipping, handling, and storage. In addition to warning about this
16 condition, Emery requested agency directives to manufacturers and distributors to ship Ranitidine-
17 Containing Products in temperature-controlled vehicles.

18 74. In response,¹⁸ on April 1, 2020, the FDA recounted that a recall is an “effective methods
19 [sic.] of removing or correcting defective FDA-regulated products . . . particularly when those products
20 present a danger to health.”¹⁹ The FDA sought the voluntary consent of manufacturers to accept the
21 recall “to protect the public health from products that present a risk of injury.”²⁰ The FDA found that the
22 recall of all Ranitidine-Containing Products and public warning of the recall was necessary because the
23

24 ¹⁵ *Id.*

25 ¹⁶ <https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-tests-ranitidine>.

26 ¹⁷ <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine>.

27 ¹⁸ Letter of Janet Woodcock, Docket No. FDA-2020-P-0042 (April 1, 2020), *available at*
<https://emerypharma.com/wp-content/uploads/2020/04/FDA-2020-P-0042-CP-Response-4-1-2020.pdf>.

28 ¹⁹ *Id.*, citing 21 CFR 7.40(a).

²⁰ *Id.*

1 “product being recalled presents a serious health risk.”²¹ The FDA therefore sent Information Requests
2 to all applicants and pending applicants of Ranitidine-Containing Products “requesting a market
3 withdrawal.”²²

4 75. The FDA found its stability testing raised concerns that NDMA levels in some ranitidine
5 products stored at room temperature can increase with time to unacceptable levels. Other testing
6 conducted by FDA revealed a correlation between NDMA levels and expiration date. The FDA’s testing
7 eroded the agency’s confidence that any ranitidine product could remain stable through its labeled
8 expiration date. Consequently, the FDA was compelled to order the products off the market. The FDA’s
9 decision to ban the drug rendered moot Emery’s request for temperature-controlled sales conditions.

10 76. The FDA therefore issued a public statement requesting the immediate removal of all
11 Ranitidine-Containing Products from the market due to the risk to public health.²³ “The agency has
12 determined that the impurity in some ranitidine products increases over time and when stored at higher
13 than room temperatures and may result in consumer exposure to unacceptable levels of this impurity.”
14 Based upon its own testing and evaluation, the FDA concluded that “NDMA levels increase in ranitidine
15 even under normal storage conditions and NDMA has been found to increase significantly in samples
16 stored at higher temperatures, including temperatures the product may be exposed to during distribution
17 and handling by consumers.”

18 77. The FDA’s reaction to the NDMA crisis involving ranitidine has come under attack. Over
19 43 different countries and jurisdictions took action to restrict or ban ranitidine-containing products before
20 the FDA took any action.²⁴ Indeed, despite being notified of the problem by Valisure in June 2019, the
21 FDA left the drug on the market for nearly an entire year, during which time countless more individuals
22 were exposed to a carcinogen against their will.

23 _____
24 ²¹ *Id.*

25 ²² *Id.*, fn. 43.

26 ²³ Press Release, *FDA Requests Removal of All Ranitidine Products (Zantac) from the Market*, U.S.
Food and Drug Administration (April 1, 2020), available at <https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market>

27 ²⁴ Margaret Newkirk and Susan Berfield, *FDA recalls are always voluntary and sometimes*
28 *haphazard—and the agency doesn’t want more authority to protect consumers*, Bloomberg
Businessweek (Dec. 3, 2019), available at <https://www.bloomberg.com/graphics/2019-voluntary-drug-recalls-zantac/>.

III. Dangers of NDMA

78. According to the U.S. Environmental Protection Agency (“EPA”), “NDMA is a semivolatile chemical that forms in both industrial and natural processes.”²⁵ It is one of the simplest members of a class of N-nitrosamines, a family of potent carcinogens. The dangers that NDMA poses to human health have long been recognized. A news article published in 1979 noted that “NDMA has caused cancer in nearly every laboratory animal tested so far.”²⁶ NDMA is no longer produced or commercially used in the United States, except for research, such as a tumor initiator in animal bioassays. In other words, the only use for NDMA today is to cause cancer in laboratory animals.

79. Both the EPA and the International Agency for Research on Cancer (“IARC”) have classified NDMA as a probable human carcinogen.²⁷

80. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.²⁸

81. The U.S. Department of Health and Human Services (“DHHS”) states that NDMA is reasonably anticipated to be a human carcinogen.²⁹ This classification is based upon DHHS’s findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney,

²⁵ United States Environmental Protection Agency, Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA) (Nov. 2017), https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf (last visited Apr. 15, 2020).

²⁶ Jane Brody, *Bottoms Up: Alcohol in moderation can extend life*, The Globe and Mail (CANADA) (Oct. 11, 1979); see Rudy Platiel, *Anger grows as officials unable to trace poison in reserve’s water*, The Globe and Mail (CANADA) (Jan. 6, 1990) (reporting that residents of Six Nations Indian Reserve “have been advised not to drink, cook or wash in the water because testing has found high levels of N-nitrosodimethylamine (NDMA), an industrial byproduct chemical that has been linked to cancer”); Kyrtopoulos et al, *DNA adducts in humans after exposure to methylating agents*, 405 MUT. RES. 135 (1998) (noting that “chronic exposure of rats to very low doses of NDMA gives rise predominantly to liver tumors, including tumors of the liver cells (hepatocellular carcinomas), bile ducts, blood vessels and Kupffer cells”).

²⁷ See EPA Technical Fact Sheet, *supra*; International Agency for Research on Cancer (IARC) - Summaries & Evaluations, N-NITROSODIMETHYLAMINE (1978), <http://www.inchem.org/documents/iarc/vol17/n-nitrosodimethylamine.html> (last visited Apr. 15, 2020).

²⁸ https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

²⁹ *Id.* at 3.

1 and blood vessels.³⁰

2 82. The FDA considers NDMA a chemical that “could cause cancer” in humans.³¹

3 83. The World Health Organization (“WHO”) states that there is “conclusive evidence that
4 NDMA is a potent carcinogen” and that there is “clear evidence of carcinogenicity.”³²

5 84. As early as 1980, consumer products containing unsafe levels of NDMA and other
6 nitrosamines have been recalled by manufacturers, either voluntarily or at the direction of the FDA.

7 85. Since the summer of 2018, there have been recalls of several generic drugs used to treat
8 high blood pressure and heart failure—Valsartan, Losartan, and Irbesartan—because the medications
9 contained nitrosamine impurities that do not meet the FDA’s safety standards.

10 86. The no-observed-adverse-effect level (“NOAEL”) is the level of exposure at which there
11 is not a biologically or significant increase in the frequency or severity of any adverse effects of the
12 chemical. Due to NDMA’s ability to affect DNA at a microscopic level, there is no NOAEL for NDMA.
13 This means any amount of NDMA exposure increases risk.

14 87. That said, the FDA has set an acceptable daily intake (“ADI”) level for NDMA at 96
15 nanograms. This means, according to the FDA, consumption of 96 nanograms of NDMA a day would
16 increase the risk of developing cancer by 0.001% over the course of a lifetime. That risk increases as the
17 level of NDMA exposure increases. However, any level above 96 nanograms is considered
18 unacceptable.³³ For example, tobacco smoke also contains NDMA. One filtered cigarette contains
19 between 5 to 43 nanograms of NDMA.

20 88. In mouse studies examining the carcinogenicity of NDMA through oral administration,
21 animals exposed to NDMA developed cancer in the kidney, bladder, liver, and lung. In comparable rat
22 studies, similar cancers were observed in the liver, kidney, pancreas, and lung. In comparable hamster
23

24 ³⁰ https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

25 ³¹ <https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine>

26 ³² World Health Organization, *Guidelines for Drinking Water Quality, N-Nitrosodimethylamine (NDMA)* (3rd ed. 2008), available at https://www.who.int/water_sanitation_health/dwq/chemicals/ndmasummary_2ndadd.pdf.

27 ³³ <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan>.

1 studies, similar cancers were observed in the liver, pancreas, and stomach. In comparable Guinea-pig
2 studies, similar cancers were observed in the liver and lung. In comparable rabbit studies, similar cancers
3 were observed in the liver and lung.

4 89. In other long-term animal studies in mice and rats utilizing different routes of
5 exposures—inhalation, subcutaneous injection, and intraperitoneal (abdomen injection)—cancer was
6 observed in the lung, liver, kidney, nasal cavity, and stomach.

7 90. Prior to the agency’s ban on Ranitidine-Containing Drugs, the FDA considered the drug
8 as category B for birth defects, meaning it was considered safe to take during pregnancy. However, in
9 animal experiments, for those animals exposed to NDMA during pregnancy, the offspring had elevated
10 rates of cancer in the liver and kidneys.

11 91. NDMA is, itself, a very small molecule. This allows it to freely pass through all areas of
12 the body, including the blood-brain and placental barrier. This is particularly concerning as ranitidine
13 has been marketed for pregnant women and young children for years.

14 92. In addition, NDMA breaks down into various derivative molecules that, themselves, are
15 associated with causing cancer. In animal studies, derivatives of NDMA induced cancer in the stomach
16 and intestine (including colon).

17 93. Research shows that lower levels of NDMA, *i.e.*, 40 ng, are fully metabolized in the liver,
18 but high doses enter the body’s general circulation.

19 94. Numerous *in vitro* studies confirm that NDMA is a mutagen—causing mutations in
20 human and animal cells.

21 95. Overall, the animal data demonstrates that NDMA is carcinogenic in all animal species
22 tested: mice, rats, Syrian golden, Chinese and European hamsters, guinea-pigs, rabbits, ducks,
23 mastomys, fish, newts, and frogs.

24 96. Pursuant to the EPA cancer guidelines, “tumors observed in animals are generally
25 assumed to indicate that an agent may produce tumors in humans.”³⁴

26 97. In addition to the overwhelming animal data linking NDMA to cancer, there are numerous
27 human epidemiological studies exploring the effects of dietary exposure to various cancers. And, while

28 ³⁴ See https://www3.epa.gov/airtoxics/cancer_guidelines_final_3-25-05.pdf.

1 these studies (several discussed below) consistently show increased risks of various cancers, the
2 exposure levels considered in these studies are a very small fraction—as little as 1 millionth—the
3 exposures noted in a single Zantac capsule, *i.e.*, 0.191 ng/day (dietary) v. 304,500 ng/day (Zantac).

4 98. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with
5 220 cases, researchers observed a statistically significant 700% increased risk of gastric cancer in persons
6 exposed to more than 0.51 ng/day.³⁵

7 99. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with
8 746 cases, researchers observed statistically significant elevated rates of gastric cancer in persons
9 exposed to more than 0.191 ng/day.³⁶

10 100. In another 1995 epidemiological case-control study looking at, in part, the effects of
11 dietary consumption on cancer, researchers observed a statistically significant elevated risk of
12 developing aerodigestive cancer after being exposed to NDMA at .179 ng/day.³⁷

13 101. In a 1999 epidemiological cohort study looking at NDMA dietary exposure with 189
14 cases and a follow up of 24 years, researchers noted that “*N*-nitroso compounds are potent carcinogens”
15 and that dietary exposure to NDMA more than doubled the risk of developing colorectal cancer.³⁸

16 102. In a 2000 epidemiological cohort study looking at occupational exposure of workers in
17 the rubber industry, researchers observed significant increased risks for NDMA exposure for esophagus,
18 oral cavity, pharynx, prostate, and brain cancer.³⁹

19 103. In a 2011 epidemiological cohort study looking at NDMA dietary exposure with 3,268
20 cases and a follow up of 11.4 years, researchers concluded that “[d]ietary NDMA intake was
21 significantly associated with increased cancer risk in men and women” for all cancers, and that “NDMA
22

23 ³⁵ Pobel, *et al.*, *Nitrosamine, nitrate and nitrite in relation to gastric cancer: a case-control study in*
24 *Marseille, France*, 11 *EUROP. J. EPIDEMIOL.* 67–73 (1995).

25 ³⁶ La Vecchia, *et al.*, *Nitrosamine intake and gastric cancer risk*, 4 *EUROP. J. CANCER. PREV.* 469–474
(1995).

26 ³⁷ Rogers, *et al.*, *Consumption of nitrate, nitrite, and nitrosodimethylamine and the risk of upper*
aerodigestive tract cancer, 5 *CANCER EPIDEMIOL. BIOMARKERS PREV.* 29–36 (1995).

27 ³⁸ Knekt, *et al.*, *Risk of Colorectal and Other Gastro-Intestinal Cancers after Exposure to Nitrate,*
Nitrite and N-nitroso Compounds: A Follow-Up Study, 80 *INT. J. CANCER* 852–856 (1999)

28 ³⁹ Straif, *et al.*, *Exposure to high concentrations of nitrosamines and cancer mortality among a cohort*
of rubber workers, 57 *OCCUP ENVIRON MED* 180–187 (2000).

was associated with increased risk of gastrointestinal cancers” including rectal cancers.⁴⁰

104. In a 2014 epidemiological case-control study looking at NDMA dietary exposure with 2,481 cases, researchers found a statistically significant elevated association between NDMA exposure and colorectal cancer.⁴¹

105. In addition to studies demonstrating that NDMA directly causes cancer, research shows that exposure to NDMA (1) can exacerbate existing but dormant cancers (*i.e.*, not malignant), (2) promote otherwise “initiated cancer cells” to develop into cancerous tumors; and (3) reduce the ability of the body to combat cancer. Thus, in addition to NDMA being a direct cause of cancer itself, NDMA can also be a contributing factor to a cancer injury caused by some other source.

106. NDMA is also known to be genotoxic – meaning, it can cause DNA damage in human cells. Indeed, multiple studies demonstrate that NDMA is genotoxic both *in vivo* and *in vitro*. However, recent studies have shown that the ability of NDMA to cause mutations in cells is affected by the presence of enzymes typically found in living humans, suggesting that “humans may be especially sensitive to the carcinogenicity of NDMA.”⁴²

IV. How Ranitidine Transforms into NDMA Within the Human Body

107. The NDMA contained in ranitidine-containing products is not caused by any direct contamination. Rather, the ranitidine molecule, itself, contains the constituent molecules to form NDMA. See Figure 1.

///

///

///

///

///

⁴⁰ Loh, *et al.*, *N-nitroso compounds and cancer incidence: the European Prospective Investigation into Cancer and Nutrition (EPIC)–Norfolk Study*, 93 AM J CLIN NUTR. 1053–61 (2011).

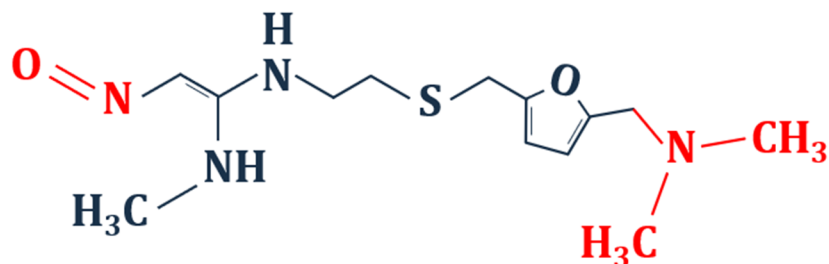
⁴¹ Zhu, *et al.*, *Dietary N-nitroso compounds and risk of colorectal cancer: a case-control study in Newfoundland and Labrador and Ontario, Canada*, 111 BR J NUTR. 6, 1109–1117 (2014).

⁴² World Health Organization, *Guidelines for Drinking Water Quality, N-Nitrosodimethylamine (NDMA)* (3rd ed. 2008), available at https://www.who.int/water_sanitation_health/dwq/chemicals/ndmasummary_2ndadd.pdf.

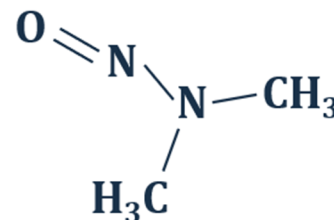
108. Specifically, the O=N (Nitroso) on one side of the ranitidine molecule can combine with the H₃C-N-CH₃ (DMA) on the other side to form NDMA. The NDMA forms out of the ranitidine

Figure 1 – Diagram of Ranitidine & NDMA Molecules

Ranitidine Molecule



NDMA Molecule



molecule itself.

109. The formation of NDMA by the reaction of DMA and a nitroso source (such as a nitrite) is well characterized in the scientific literature and has been identified as a concern for contamination of the American water supply.⁴³ Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater treatment plants was specifically linked to the presence of ranitidine.⁴⁴

110. Ranitidine leads to NDMA exposure by: (1) formation of NDMA in the human stomach; (2) formation of NDMA due to an enzymatic reaction throughout the human body; and (3) formation of NDMA due to heat and time.

A. Formation of NDMA in the Environment of the Human Stomach

111. When the ranitidine molecule is exposed to the acidic environment of the stomach, particularly when accompanied by nitrites (a chemical commonly found in heartburn-inducing foods), the Nitroso molecule (O=N) and the DMA molecule (H₃C-N-CH₃) break off and reform as NDMA.

112. In 1981, Dr. Silvio de Flora, an Italian researcher from the University of Genoa, published the results of experiments he conducted on ranitidine in the well-known journal, The Lancet. When

⁴³ Ogawa, *et al.*, *Purification and properties of a new enzyme, NG, NG-dimethylarginine dimethylaminohydrolase, from rat kidney*, 264 J. BIO. CHEM. 17, 10205-10209 (1989).

⁴⁴ Mitch, *et al.*, *N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review*, 20 ENV. ENG. SCI. 5, 389-404 (2003).

1 ranitidine was exposed to human gastric fluid in combination with nitrites, his experiment showed “toxic
2 and mutagenic effects[.]”⁴⁵ Dr. de Flora hypothesized that these mutagenic effects could have been
3 caused by the “formation of more than one nitroso derivative [which includes NDMA] under our
4 experimental conditions.” *Id.* Dr. de Flora cautioned that, in the context of ranitidine ingestion, “it would
5 seem prudent to ... suggest[] a diet low in nitrates and nitrites, by asking patients not to take these at
6 times close to (or with) meals[.]”⁴⁶ *Id.*

7 113. GSK knew of Dr. de Flora’s publication because, two weeks later, GSK responded in *The*
8 *Lancet*, claiming that the levels of nitrite needed to induce the production of nitroso derivatives (*i.e.*,
9 NDMA) were not likely to be experienced by people in the real world.⁴⁷

10 114. In its submission to the FDA, GSK explained that the level of nitrite present would be
11 unrealistic and, thus, these results had no “practical clinical significance”⁴⁸:

12 Although N-nitroso-nitrolic acid was a potent mutagen, it is
13 not likely to be formed in the stomach of a patient ingesting
14 ranitidine, as an unrealistically large amount of nitrite
15 needs to be present to form and maintain the nitrosamine. For
16 this reason, and also because ranitidine was not carcinogenic
17 in life-span studies in rodents, the in vitro nitrosation of
18 ranitidine to a mutagenic nitrosamine does not seem to have
19 practical clinical significance.
20
21
22

23 ⁴⁵ De Flora, *Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives*, *THE LANCET* 993-994
(Oct. 31, 1981).

24 ⁴⁶ This admonition came two years before the FDA’s approved Zantac in 1983. Notwithstanding, in
25 1998 GSK applied for and obtained an indication for OTC Zantac “[f]or the prevention of meal-
26 induced heartburn at a dose of 75 mg taken 30 to 60 minutes prior to a meal.” *See*
https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/20520s1_Zantac.pdf. So, GSK specifically
invited patients to take Zantac shortly before eating heartburn-inducing food.

27 ⁴⁷ R. T., Brittain, et al, *Safety of Ranitidine*, *THE LANCET* (Nov. 14, 1981).

28 ⁴⁸ Excerpted from the Summary Basis of Approval submitted to the FDA to obtain approval of Zantac
in the early 1980s. This document was obtained through a Freedom of Information Act request to the
FDA.

1 115. Around this same time—before Zantac was approved by the FDA—GSK conducted
2 another study to examine, among other things, how long-term use of ranitidine could affect the levels of
3 nitrite in the human stomach.⁴⁹ Remarkably, in the study that was presented to the FDA, GSK admitted
4 that ranitidine use caused the proliferation of bacteria in the human stomach that are known to convert
5 nitrates to nitrites, which leads to elevated levels of nitrite in the stomach environment. GSK
6 acknowledged this could increase the risk of developing NDMA and, in turn, cancer, but then dismissed
7 this risk because people were only expected to use ranitidine-containing products for a short-term period:

8 **The importance of this finding is not clear. High levels of**
9 **nitrite could react with certain organic compounds to form**
10 **nitrosamines, which are known carcinogens. To date, however,**
11 **neither ranitidine nor cimetidine have been carcinogenic in**
12 **rodents, so the level of human risk cannot be estimated from**
13 **animal studies. Ranitidine is recommended only for short-term**
14 **use and carcinogenic risk, if any, should thus be minimized.**

15 116. GSK knew—and indeed specifically admitted—that ranitidine could react with nitrite in
16 the human stomach to form NDMA and, at the same time, that long-term use of ranitidine could lead to
17 elevated levels of nitrite in the human stomach.

18 117. In response to Dr. de Flora's findings, in 1982, GSK conducted a clinical study
19 specifically investigating gastric contents in human patients.⁵⁰ The study, in part, specifically measured
20 the levels of N-Nitroso compounds in human gastric fluid. GSK indicated that there were no elevated
21 levels, and even published the results of this study five years later, in 1987. The study, however, was
22 rigged. It did not use gold-standard mass spectrometry to test for NDMA, but instead, used a process
23 that could not measure N-nitrosamines efficiently. And worse, in the testing it did do, GSK refused to
24 test gastric samples that contained ranitidine in them out of concern that samples with ranitidine would
25 contain "high concentrations of N-nitroso compounds being recorded." *Id.* So, GSK did not test for
26 NDMA in any gastric fluid that contained ranitidine.

27 118. In 1983, the same year Zantac obtained approval from the FDA, seven researchers from
28

⁴⁹ The results of this study are discussed in the Summary Basis of Approval, obtained from the FDA.

⁵⁰ Thomas, *et al.*, *Effects of one year's treatment with ranitidine and of truncal vagotomy on gastric contents*, 6 *GUT*. Vol. 28, 726-738 (1987).

1 the University of Genoa published a study discussing ranitidine and its genotoxic effects (ability to harm
2 DNA).⁵¹ The researchers concluded “it appears that reaction of ranitidine with excess sodium nitrite
3 under acid conditions gives rise to a nitroso-derivative (or derivatives) [like NDMA] capable of inducing
4 DNA damage in mammalian cells.” *Id.*

5 119. Then, again in 1983, Dr. de Flora, along with four other researchers, published their
6 complete findings.⁵² The results “confirm our preliminary findings on the formation of genotoxic
7 derivatives from nitrite and ranitidine[.]” *Id.* Again, the authors noted that, “the widespread clinical use
8 [of ranitidine] and the possibility of a long-term maintenance therapy suggest the prudent adoption of
9 some simple measures, such as a diet low in nitrates and nitrites or the prescription of these anti-ulcer
10 drugs at a suitable interval from meals.” *Id.* This admonition carries weight considering GSK’s studies
11 indicate that long-term ranitidine consumption, itself, leads to elevated levels of nitrites in the human
12 gut.

13 120. The high instability of the ranitidine molecule was elucidated in scientific studies
14 investigating ranitidine as a source of NDMA in drinking water and specific mechanisms for the
15 breakdown of ranitidine were proposed.⁵³ These studies underscore the instability of the NDMA group
16 on the ranitidine molecule and its ability to form NDMA in the environment of water treatment plants
17 which supply many American cities with water.

18 121. In 2016, researchers at Stanford University conducted an experiment on healthy
19 volunteers (Stanford Study).⁵⁴ They measured the NDMA in urine of healthy individuals over the course
20 of 24 hours, administered one dose of ranitidine, and then measured the NDMA in the urine of the same
21 individuals for another 24 hours. On average, the level of NDMA increased by 400 times, to
22 approximately 47,000 nanograms. The only change during that 24-hour period was the consumption of
23 ranitidine. This study directly demonstrated that unsafe levels of NDMA are formed in the human body
24

25 ⁵¹ Maura, *et al.*, *DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells*, 18
TOX. LTTRS. 97-102 (1983).

26 ⁵² De Flora, *et al.*, *Genotoxicity of nitrosated ranitidine*, 4 CARCINOGENESIS 3, 255-260 (1983).

27 ⁵³ Le Roux, *et al.*, *NDMA Formation by Chloramination of Ranitidine: Kinetics and Mechanism*, 46
Environ. Sci. Technol. 20, 11095-11103 (2012).

28 ⁵⁴ Zeng, *et al.*, *Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine*, 37
CARCINOGENESIS 625-634 (2016).

as a result of ranitidine ingestion. The scientists further explained that humans do not typically excrete NDMA in their urine, so that the observed 47,000 nanograms likely only captured 1/100 of the actual NDMA levels in the human body.

122. These studies did not appreciate the full extent of NDMA formation risk from ranitidine; specifically, the added danger of this drug having not only a labile DMA group but also a readily available nitroso source in its nitrite group on the opposite terminus of the molecule. Recent testing reveals that NDMA levels in ranitidine batches are so high that the nitroso for NDMA likely comes from no other source than the ranitidine molecule itself.

123. Valisure is an online pharmacy that also runs an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization (“ISO”) – an accreditation recognizing the laboratories technical competence for regulatory. Valisure’s mission is to help ensure the safety, quality, and consistency of medications and supplements in the market. In response to rising concerns about counterfeit medications, generics, and overseas manufacturing, Valisure developed proprietary analytical technologies that it uses in addition to FDA standard assays to test every batch of every medication it dispenses.

124. In its September 9, 2019, Citizen’s Petition to the FDA, Valisure disclosed as part of its testing of Zantac, and other ranitidine-containing products that in every lot tested there were exceedingly high levels of NDMA discovered. Valisure’s ISO 17025 accredited laboratory used FDA recommended GC/MS headspace analysis method FY19-005-DPA8 for the determination of NDMA levels. As per the FDA protocol, this method was validated to a lower limit of detection of 25 ng.⁵⁵ The results of Valisure’s testing show levels of NDMA well above 2 million ng per 150 mg Zantac tablet, shown below in Table 1.

Table 1 – Ranitidine Samples Tested by Valisure Laboratory Using GC/MS Protocol		
150 mg Tablets or equivalent	Lot #	NDMA per tablet (ng)
Reference Powder*	125619	2,472,531

⁵⁵ US Food and Drug Administration. (updated 01/25/2019). Combined N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay, *FY19-005-DPA-S*.

1	Zantac, Brand OTC	18M498M	2,511,469
2	Zantac (mint), Brand OTC	18H546	2,834,798
3	Wal-Zan, Walgreens	79L800819A	2,444,046
4	Wal-Zan (mint), Walgreens	8ME2640	2,635,006
5	Ranitidine, CVS	9BE2773	2,520,311
6	Zantac (mint), CVS	9AE2864	3,267,968
7	Ranitidine, Equate	9BE2772	2,479,872
8	Ranitidine (mint), Equate	8ME2642	2,805,259
9	Ranitidine, Strides	77024060A	2,951,649

125. Valisure's testing shows, on average, 2,692,291 ng of NDMA in a 150 mg Zantac tablet. Considering the FDA's permissible limit is 96 ng, this would put the level of NDMA at 28,000 times the legal limit. In terms of smoking, a person would need to smoke at least 6,200 cigarettes to achieve the same levels of NDMA found in one 150 mg dose of Zantac.

126. Valisure, however, was concerned that the extremely high levels of NDMA observed in its testing were a product of the modest oven heating parameter of 130 °C in the FDA recommended GC/MS protocol. So, Valisure developed a low temperature GC/MS method that could still detect NDMA but would only subject samples to 37 °C, the average temperature of the human body. This method was validated to a lower limit of detection of 100 ng.

127. Valisure tested ranitidine tablets by themselves and in conditions simulating the human stomach. Industry standard "Simulated Gastric Fluid" ("SGF" 50 mM potassium chloride, 85 mM hydrochloric acid adjusted to pH 1.2 with 1.25 g pepsin per liter) and "Simulated Intestinal Fluid" ("SIF" 50 mM potassium chloride, 50 mM potassium phosphate monobasic adjusted to pH 6.8 with hydrochloric acid and sodium hydroxide) were used alone and in combination with various concentrations of nitrite, which is commonly ingested in foods like processed meats and is elevated in the stomach by antacid drugs. The inclusion of nitrite in gastric fluid testing is commonplace and helps simulate the environment of a human stomach.

128. Indeed, Zantac was specifically advertised to be used when consuming foods containing

high levels of nitrates, like tacos, pizza, *etc.*⁵⁶

129. The results of Valisure’s tests on ranitidine tablets in biologically relevant conditions demonstrate significant NDMA formation under simulated gastric conditions with nitrite present (*see* Table 2).

Table 2 – Valisure Biologically Relevant Tests for NDMA Formation		
Ranitidine Tablet Studies	NDMA (ng/mL)	NDMA per tablet (ng)
Tablet without Solvent	Not Detected	Not Detected
Tablet	Not Detected	Not Detected
Simulated Gastric Fluid (“SGF”)	Not Detected	Not Detected
Simulated Intestinal Fluid	Not Detected	Not Detected
SGF with 10 mM Sodium Nitrite	Not Detected	Not Detected
SGF with 25 mM Sodium Nitrite	236	23,600
SGF with 50 mM Sodium Nitrite	3,045	304,500

130. Under biologically relevant conditions, when nitrites are present, high levels of NDMA are found in one dose of 150 mg Zantac, ranging between 245 and 3,100 times above the FDA-allowable limit. In terms of smoking, one would need to smoke over 500 cigarettes to achieve the same levels of NDMA found in one dose of 150 mg Zantac at the 25 nanogram level (over 7,000 for the 50 nanogram level).

131. When the scientific data is assessed overall, the literature demonstrates that the ingestion of ranitidine in the presence of human-relevant levels of nitrite in the stomach—a substance that is commonly found in foods that induce heartburn and that is known to be elevated in people taking ranitidine for longer than a month—the ranitidine molecule breaks down into levels of NDMA that would dramatically increase a person’s risk of developing cancer.

B. Formation of NDMA in the Other Organs of Human Body

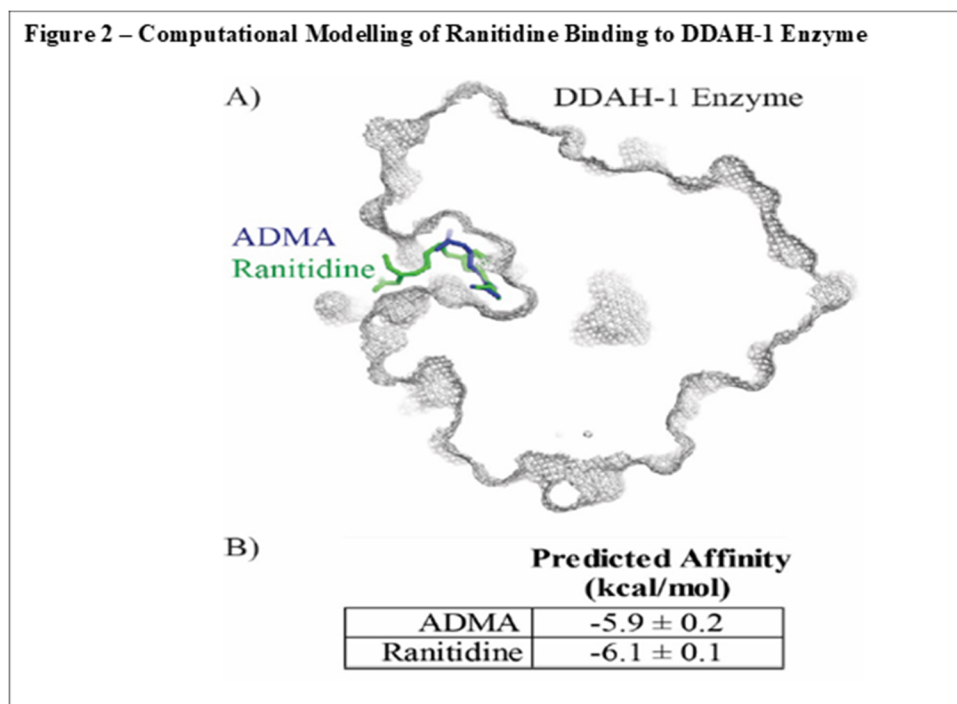
132. In addition to the gastric fluid mechanisms investigated in the scientific literature, Valisure identified a possible enzymatic mechanism for the liberation of ranitidine’s DMA group via the human enzyme dimethylarginine dimethylaminohydrolase (“DDAH”), which can occur in other tissues

⁵⁶ See, e.g., <https://www.ispot.tv/ad/dY7n/zantac-family-taco-night>; https://youtu.be/jzS2kuB5_wg; <https://youtu.be/Z3QMwkSUIEg>; <https://youtu.be/qvh9gyWqQns>.

and organs separate from the stomach.

133. Liberated DMA can lead to the formation of NDMA when exposed to nitrite present on the ranitidine molecule, nitrite freely circulating in the body, or other potential pathways, particularly in weak acidic conditions such as that in the kidney or bladder. The original scientific paper detailing the discovery of the DDAH enzyme in 1989 specifically comments on the propensity of DMA to form NDMA: “This report also provides a useful knowledge for an understanding of the endogenous source of dimethylamine as a precursor of a potent carcinogen, dimethylnitrosamine [NDMA].”⁵⁷

134. In Figure 2, below, computational modelling demonstrates that ranitidine (shown in green) can readily bind to the DDAH-1 enzyme (shown as a cross-section in grey) in a manner similar to the natural substrate of DDAH-1 known as asymmetric dimethylarginine (“ADMA,” shown in blue).

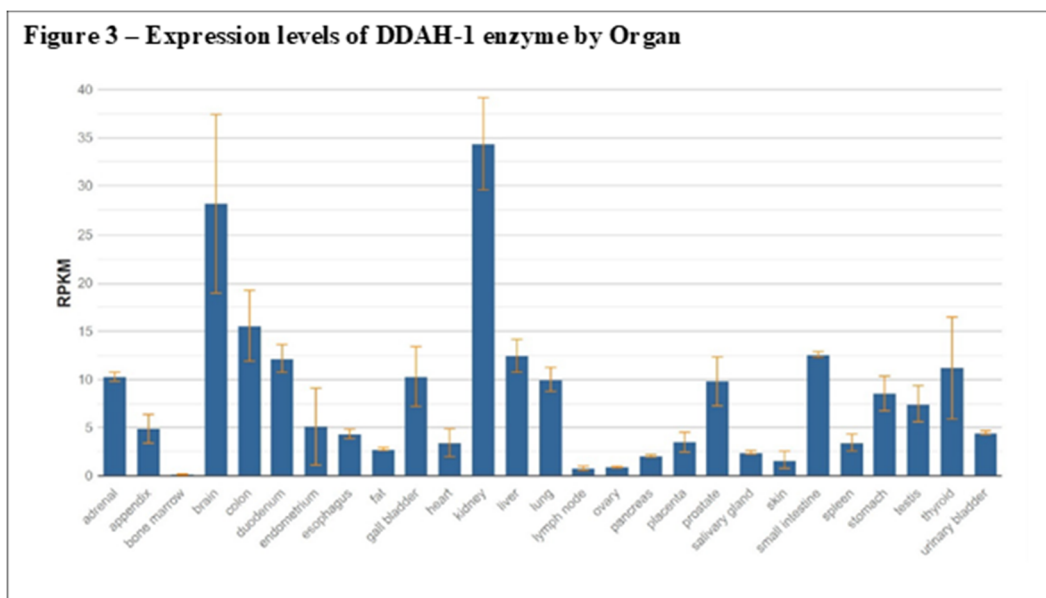


135. These results indicate that the enzyme DDAH-1 increases formation of NDMA in the human body when ranitidine is present; therefore, the expression of the DDAH-1 gene is useful for identifying organs most susceptible to this action.

136. Figure 3 below, derived from the National Center for Biotechnology Information,

⁵⁷ Ogawa, et al., *Purification and properties of a new enzyme, NG, NG-dimethylarginine dimethylaminohydrolase, from rat kidney*, 264 *J. BIO. CHEM.* 17, 10205-10209 (1989).

illustrates the expression of the DDAH-1 gene in various tissues in the human body.



137. DDAH-1 is most strongly expressed in the kidneys but also broadly distributed throughout the body, such as in the liver, prostate, stomach, bladder, brain, colon, and prostate. This offers both a general mechanism for NDMA formation in the human body from ranitidine and specifically raises concern for the effects of NDMA on numerous organs, including the bladder.

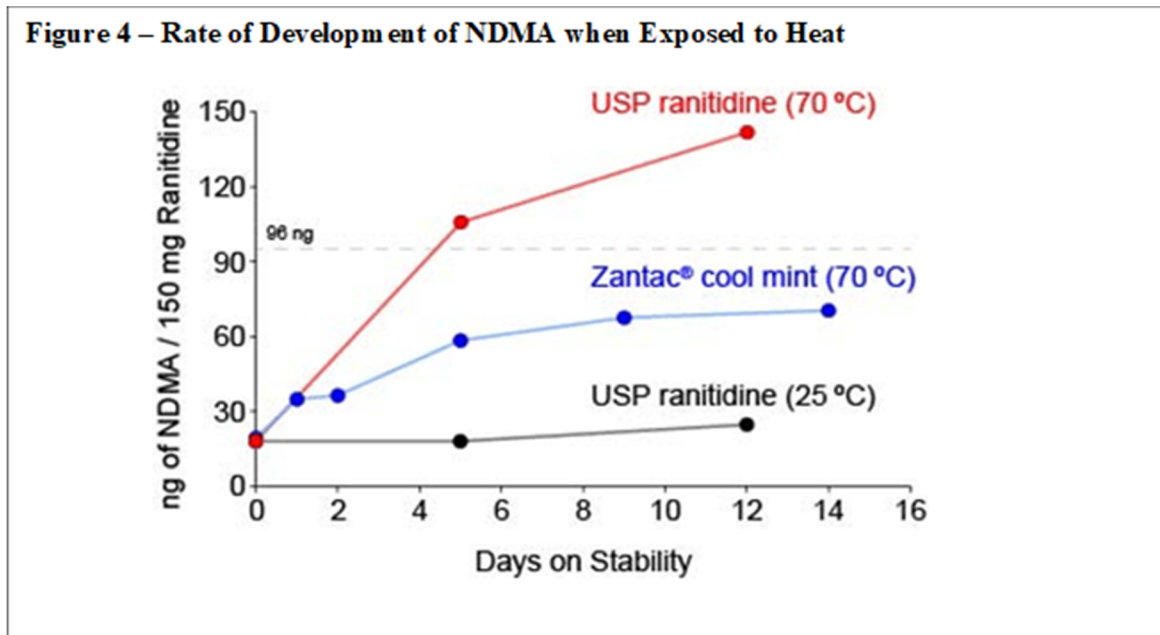
138. The possible enzymatic reaction of ranitidine to DDAH-1, or other enzymes, suggests that high levels of NDMA can form throughout the human body. Indeed, ranitidine metabolizes and circulates throughout the human body, crossing the placental and blood-brain barrier, within 1-2 hours. When the ranitidine interacts with the DDAH-1 enzyme in various organs throughout the body, it breaks down into NDMA. This observation is validated by the Stanford study.

C. Formation of NDMA by Exposure to Heat and/or Time

139. The risk of creating NDMA by exposing ranitidine to heat has been well-known and documented. Early studies, including the one conducted by GSK in the early 1980s, demonstrated that NDMA formed when ranitidine was exposed to heat. This point was underscored in the Valisure petition, which specifically developed a detection protocol that did not use heat.

140. In response to Valisure, on October 2, 2019, the FDA recommended that researchers use the LC-HRMS protocol for detecting NDMA in ranitidine because the “testing method does not use elevated temperatures” and has been proven capable of detecting NDMA.

141. On January 2, 2020, Emery Pharma, an FDA-certified pharmaceutical testing laboratory, conducted a series of tests on ranitidine using the FDA-recommended LC-HRMS protocol. The researchers exposed ranitidine to 70 °C for varying periods of time. The results showed that increasing levels of NDMA formed based on exposure to heat. The following diagram reveals how NDMA accumulates over time when exposed to 70 °C:



142. The researchers cautioned:

NDMA accumulates in ranitidine-containing drug products on exposure to elevated temperatures, which would be routinely reached during shipment and during storage. More importantly, these conditions occur post-lot release by the manufacturer. Hence, while NDMA levels in ranitidine may be acceptable at the source, they may not be so when the drug is purchased and subsequently at the time of consumption by the consumer.

143. Indeed, the FDA's recent testing confirms that NDMA levels increase in ranitidine even under normal storage conditions, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures to which ranitidine may be exposed during distribution and handling by retailers.⁵⁸

144. The results of this data demonstrate that in normal transport and storage, and especially

⁵⁸ Press Release, *FDA Requests Removal of All Ranitidine Products (Zantac) from the Market*, U.S. Food and Drug Administration (April 1, 2020), available at <https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market>

1 when exposed to heat, the ranitidine molecule systematically breaks down into NDMA, accumulating
2 over time in the finished product. Considering ranitidine-containing products have an approved shelf life
3 of 36 months, the possibility of the drug accumulating dangerously high levels of NDMA prior to
4 consumption is very real—a point underscored by the FDA’s removal of the product from the market.

5 **D. Evidence Also Directly Links Ranitidine Exposure to Cancer**

6 145. In addition to numerous epidemiology studies examining how NDMA causes cancer in
7 humans, researchers have also specifically looked at ranitidine and found an association with cancer.

8 146. One epidemiology study, published in 2004, showed that men taking either ranitidine or
9 cimetidine (Tagamet) had increased risks of bladder cancer.⁵⁹

10 147. In one epidemiology study specifically designed to look at breast cancer, ranitidine was
11 shown to more than double the risk of breast cancer, an effect that was even more pronounced in those
12 with specific gene mutations.⁶⁰

13 148. In another comprehensive epidemiological study looking at various cancer risks and H2
14 blockers, including ranitidine, the data showed that ranitidine consumption increased the risk of prostate,
15 lung, esophageal, pancreatic, and kidney cancer.⁶¹ Of particular note, the study indicated that people
16 under the age of 60 that took ranitidine were five times more likely to contract prostate cancer.

17 149. A study published in 2018, demonstrated an increased risk of liver cancer associated with
18 use of ranitidine in comparison with other histamine type 2 receptor antagonists (H2RAs) in the class.
19 The purpose of the study was to determine whether there was an increased risk of liver cancer associated
20 with proton pump inhibitors, a different class of medications indicated for the treatment of GERD. This
21 finding is particularly notable as the authors adjusted for variables and, more significantly, did not study
22 or consider long term use of H2RAs or the possibility of a dose dependent increase in risk.⁶²

23 150. In 2018, a study found an increased risk in hepatocellular carcinoma associated with use

24 ⁵⁹ D. Michaud, et al, *Peptic Ulcer Disease and the Risk of Bladder Cancer in a Prospective Study of*
25 *Male Health Professionals*, 13 CANCER EPI. BIOMARK. & PREV. 250–254, 252 (Feb. 2004).

26 ⁶⁰ Robert W. Mathes, et al, *Relationship between histamine2-receptor antagonist medications and risk*
27 *of invasive breast cancer*, 17 CANCER EPI. BIOMARKERS & PREVENTION 1, 67-72 (2008).

27 ⁶¹ Laurel A. Habel, et al, *Cimetidine Use and Risk of Breast, Prostate, and Other Cancers*, 9
28 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 149-155 (2000).

28 ⁶² Kim Tu Tran,, et al., *Proton pump inhibitor and histamine-2 receptor antagonist use and risk of*
liver cancer in two population-based studies, 48 ALIMENTARY PHARMA & THERAP 1, 55-64 (2018).

1 of H2RAs.⁶³ The authors were evaluating the risk of cancer in association with proton pump inhibitors
2 and looked at H2RAs as a confounder. The study only considered use of H2RAs within one year of
3 cancer diagnosis and still found an increased odds ratio associated with use of H2RAs and hepatocellular
4 carcinoma, a type of liver cancer.

5 151. A number of other studies have been published over the years showing an increased risk
6 of various cancers associated with use of ranitidine and/or H2RAs.⁶⁴

7 152. In addition, Memorial Sloan Kettering recently tested ranitidine for cancer association.
8 In January 2021, a Sloan Kettering paper demonstrated an association with cancer that showed a
9 “significant increase” in the odds of developing multiple types of cancer.

10 **V. Defendants Made False Statements in the Labeling of Their Ranitidine-Containing**
11 **Products**

12 153. A manufacturer is required to give adequate directions for the use of a pharmaceutical
13 drug such that a “layman can use a drug safely and for the purposes for which it is intended,”⁶⁵ and
14 conform to requirements governing the appearance of the label.⁶⁶

15 154. “Labeling” encompasses all written, printed or graphic material accompanying the drug
16 or device,⁶⁷ and therefore broadly encompasses nearly every form of promotional activity, including not
17 only “package inserts” but also advertising.

18 155. “Most, if not all, labeling is advertising. The term “labeling” is defined in the FDCA as
19 including all printed matter accompanying any article. Congress did not, and we cannot, exclude from
20

21 _____
22 ⁶³ Shao, Y-HJ, et al., *Association between proton pump inhibitors and the risk of hepatocellular*
carcinoma, 48 ALIMENTARY PHARMA & THERAP 4, 460-468 (2018).

23 ⁶⁴ Robert W. Mathes, et al., *Relationship between histamine2-receptor antagonist medications and risk*
of invasive breast cancer, 17 CANCER EPID. & PREV BIOMARKERS 1, 67-72 (2008); *see also* Ahn, Jeong
24 Soo, et al., *Acid suppressive drugs and gastric cancer: a meta-analysis of observational studies*, 19
WORLD J. GASTROENTEROLOGY 16, 2560 (2013); Lai, Shih-Wei, et al., *Use of proton pump inhibitors*
25 *correlates with increased risk of pancreatic cancer: a case-control study in Taiwan*, 46 KUWAIT MED
J. 1, 44-48 (2014); Poulsen et al., *Proton Pump Inhibitors and risk of gastric cancer – a population*
26 *based cohort study*, 100 BRITISH J CANCER 1503-1507 (2009); E Wennerström, *Acid-suppressing*
therapies and subsite-specific risk of stomach cancer, 116 BRITISH J CANCER 9, 1234-1238 (2017).

27 ⁶⁵ 21 C.F.R. § 201.5.

28 ⁶⁶ 21 C.F.R. § 801.15.

⁶⁷ Id. 65 Fed. Reg. 14286 (March 16, 2000).

1 the definition printed matter which constitutes advertising.”⁶⁸

2 156. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.⁶⁹

3 157. Because Defendants did not disclose NDMA as an ingredient in the Ranitidine-
4 Containing Products ingested by Edward Porras, the subject drugs were misbranded.

5 158. It is unlawful to introduce a misbranded drug into interstate commerce.⁷⁰ Thus, the
6 Ranitidine-Containing Products ingested by Edward Porras were unlawfully distributed and sold.

7 **VI. Defendants Knew or Should Have Known of the NDMA Risk**

8 159. During the time that Defendants manufactured and sold Ranitidine-Containing Drugs in
9 the United States, the weight of scientific evidence showed that Ranitidine-Containing Drugs exposed
10 users to unsafe levels of NDMA. Defendants failed to disclose this risk to consumers on the drug’s
11 label—or through any other means—and Defendants failed to report these risks to the FDA.

12 160. Going back as far as 1981, two years before Zantac entered the market, research showed
13 elevated rates of NDMA, when properly tested. This was known or should have been known by the
14 Defendants or any other maker or distributor of ranitidine-containing products.

15 161. Defendants concealed the Zantac–NDMA link from consumers in part by not reporting it
16 to the FDA, which relies on drug manufacturers (or others, such as those who submit citizen petitions)
17 to bring new information about an approved drug like Ranitidine-Containing Drugs to the agency’s
18 attention.

19 162. Manufacturers of an approved drug are required by regulation to submit an annual report
20 to the FDA containing, among other things, new information regarding the drug’s safety pursuant to 21
21 C.F.R. § 314.81(b)(2):

22 163. The report is required to contain . . . [a] brief summary of significant new information
23 from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The
24 report is also required to contain a brief description of actions the applicant has taken or intends to take
25 as a result of this new information, for example, submit a labeling supplement, add a warning to the
26

27 ⁶⁸ *U.S. v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).

28 ⁶⁹ 21 C.F.R. § 201.6; 201.10.

⁷⁰ 21 U.S.C. § 331(a).

1 labeling, or initiate a new study.

2 164. 21 C.F.R. § 314.81(b)(2)(v) provides:

3 The manufacturer's annual report also must contain copies of unpublished
4 reports and summaries of published reports of new toxicological findings in
5 animal studies and in vitro studies (e.g., mutagenicity) conducted by, or
6 otherwise obtained by, the [manufacturer] concerning the ingredients in the
7 drug product.

8 165. Defendants ignored these regulations and, disregarding the scientific evidence available
9 to them, did not report to the FDA significant new information affecting the safety or labeling of
10 Ranitidine-Containing Drugs.

11 166. Knowledge regarding the risk of NDMA in ranitidine was sufficiently available in the
12 publicly available scientific literature that any maker or distributor, consistent with their heightened
13 obligations to ensure the safety of their products, should have known about the potential NDMA risks
14 associated with ranitidine consumption.

15 167. Defendants never conducted or provided the relevant studies to the FDA, nor did they
16 present to the FDA with a proposed disclosure noting the link between ranitidine and NDMA.
17 Accordingly, because the Defendants never properly disclosed the risk to the FDA, they never proposed
18 any labeling or storage / transportation guidelines that would have addressed this risk. Thus, the FDA
19 was never able to reject any proposed warning or proposal for transport / storage.

20 168. Nothing prevented any Defendant from, on its own, taking actions to prevent
21 accumulation of NDMA in ranitidine drugs by ensuring cooled storage and transport. Such actions would
22 not have required FDA approval, nor would they have violated any regulatory decisions or laws.

23 169. Defendants also knew federal law requires pharmaceutical drugs to be stored,
24 warehoused, and distributed in accordance with current "Good Manufacturing Practices" ("GMPs") to
25 ensure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

26 170. 21 C.F.R. § 211.142(b) states that the GMPs required that warehousing of drug products
27 shall be performed to provide for "[s]torage of drug products under appropriate conditions of
28 temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products
are not affected." In other words, Defendants had a duty and were obligated to properly store, handle,

1 and warehouse Ranitidine-Containing Drugs.

2 171. Testing conducted by the FDA, which led to the agency's ban on Ranitidine-Containing
3 Drugs, confirms that improper storage of Ranitidine-Containing Drugs has resulted in extremely high
4 levels of NDMA. FDA has also concluded that NDMA can increase in Ranitidine-Containing Drugs
5 even under normal storage conditions. And, NDMA has been found to increase significantly in samples
6 stored at higher temperatures, including temperatures the product may be exposed to during distribution
7 and handling by consumers. FDA's testing also showed that as Ranitidine-Containing Drugs age the
8 level of NDMA in the product increases.

9 172. FDA concluded that these defects raised the level of NDMA in Ranitidine-Containing
10 Drugs above the acceptable daily intake limit to the point that the drugs had to be banned.

11 173. In a 1981 study published by GSK, the originator of the ranitidine molecule, the
12 metabolites of ranitidine in urine were studied using liquid chromatography.⁷¹ Many metabolites were
13 listed, though there is no indication that NDMA was looked for. Plaintiff believes this was intentional—
14 a gambit by the manufacturer to avoid detecting a carcinogen in their product. All Defendants knew or
15 should have known about this study and, therefore, were obligated to investigate this issue properly.
16 None did.

17 174. Indeed, in that same year, Dr. de Flora published a note in *The Lancet* discussing the
18 results of his experiments showing that ranitidine was turning into mutagenic N-nitroso compounds, of
19 which NDMA is one, in human gastric fluid when accompanied by nitrites – a substance commonly
20 found in food and in the body. GSK was aware of this as GSK specifically responded to the note and
21 attempted to discredit it. Defendants knew or should have known about this scientific exchange as it was
22 in a popular scientific journal, *The Lancet*. Therefore, the Defendants were obligated to investigate this
23 issue properly, and none did.

24 175. By 1987, after numerous studies raised concerns over ranitidine and cancerous nitroso
25 compounds (discussed previously), GSK published a clinical study specifically investigating gastric
26

27 ⁷¹ Carey, *et al.*, *Determination of ranitidine and its metabolites in human urine by reversed-phase ion-*
28 *pair high-performance liquid chromatography*, 255 J. CHROMATOGRAPHY B: BIOMEDICAL SCI. & APPL.
1, 161-168 (1981).

1 contents in human patients and N-nitroso compounds.⁷² This study specifically indicated that there were
2 no elevated levels of N-nitroso compounds (of which NDMA is one). However, the study was rigged to
3 fail. It used an analytical system called a “nitrogen oxide assay” for the determination of N-nitrosamines,
4 which was developed for analyzing food and is a detection method that indirectly and non-specifically
5 measures N-nitrosamines. Furthermore, in addition to this approach being less accurate, GSK also
6 removed all gastric samples that contained ranitidine out of concern that samples with ranitidine would
7 contain “high concentrations of N-nitroso compounds being recorded.” So, without the chemical being
8 present in any sample, any degradation into NDMA could not, by design, be observed. Again, this
9 spurious test was intentional and designed to mask any potential cancer risk. The inadequacy of this test
10 was knowable in light of its scientific publication in 1987. All Defendants either knew or should have
11 known about the inadequacy of this study and should have investigated the issue properly and/or took
12 action to protect consumers from the NDMA risks in their products. None did.

13 176. In fact, upon information and belief, none of the Defendants ever used a mass
14 spectrometry assay to test for the presence of nitrosamines in any of the studies and trials they did in
15 connection with their trials associated with the ranitidine NDA. That is because when using mass
16 spectrometry, it requires heating of up to 130 degrees Celsius, which can result in excessive amounts of
17 nitrosamines being formed. Had the Defendants used a mass spectrometry assay, it would have revealed
18 in the finding of large amounts of NDMA, and the FDA would never have approved Zantac as being
19 safe.

20 177. Based on the public scientific information available starting in 1983 (or earlier), the
21 Defendants knew or should have known that NDMA could form in ranitidine by exposure to heat and/or
22 over time in storage. No Defendants, upon information and belief, took action to reduce this risk through
23 altering supply-chain conduct or warning consumers. Additionally, no Defendants took any action to
24 further investigate this issue notwithstanding the signal that existed in the scientific literature.

25 178. Although the labels for Ranitidine-Containing Drugs do not warn of any NDMA or cancer
26 risk, Defendants were aware of the dangers of exposing Ranitidine-Containing Drugs to excess heat—
27

28 ⁷² Thomas, *et al.*, *Effects of one year's treatment with ranitidine and of truncal vagotomy on gastric contents*, 6 *GUT*. Vol. 28, 726-738 (1987).

1 but failed to take steps to reduce NDMA accumulation –given that each Zantac *box* states, “to avoid
2 excessive heat” and to keep the drug below 77°F:

3 **Other information**

- 4 • do not use if individual foil pouch is open or torn
• avoid excessive heat or humidity

- store at 20°-25°C (68°-77°F)
• this product is sodium and sugar free

5 179. Any distributor or seller of a Ranitidine-Containing Drug would be duty-bound to follow
6 the handling procedures and ensure the product is not exposed to temperatures above 77° F during
7 transport and storage.

8 180. There are multiple alternatives to Zantac that do not pose the same risk, such as
9 Cimetidine (Tagamet), Famotidine (Pepcid), Omeprazole (Prilosec), Esomeprazole (Nexium), and
10 Lansoprazole (Prevacid).

11 **VII. Exemplary / Punitive Damages Allegations (Against Manufacturer Defendants)**

12 181. Defendants’ conduct as alleged herein was done with reckless disregard for human life,
13 oppression, and malice. Defendants were fully aware of the safety risks of Ranitidine-Containing Drugs,
14 particularly the carcinogenic potential of Ranitidine-Containing Drugs as it transforms into NDMA
15 within the chemical environment of the human body and/or during transport and/or storage. Nonetheless,
16 Defendants deliberately crafted their label, marketing, and promotion to mislead consumers.

17 182. This was not done by accident or through some justifiable negligence. Rather, Defendants
18 knew they could profit by convincing consumers that Ranitidine-Containing Drugs was harmless to
19 humans, and that full disclosure of the true risks of Ranitidine-Containing Drugs would limit the amount
20 of money Defendants would make selling the drugs. Defendants’ object was accomplished not only
21 through a misleading label, but through a comprehensive scheme of selective misleading research and
22 testing, false advertising, and deceptive omissions as more fully alleged throughout this pleading.
23 Edward Porras was denied the right to make an informed decision about whether to purchase and use
24 Ranitidine-Containing Drugs, knowing the full risks attendant to that use. Such conduct was done with
25 conscious disregard of Edward Porras’s rights.

26 183. Accordingly, Plaintiff requests punitive damages against the Manufacturer Defendants
27 for the harms caused to Edward Porras
28

VIII. Equitable Tolling/Estoppel

184. Plaintiff asserts all applicable statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, delayed discovery, discovery rule and/or fraudulent concealment.

185. The discovery rule applies to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts that Edward Porras had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

186. The nature of Edward Porras's injuries, damages, or their causal relationship to Defendants' conduct was not discovered, and through reasonable care and due diligence could not have been discovered until a date within the applicable statute of limitations for filing Plaintiff's claims.

187. The running of the statute of limitations is tolled due to equitable tolling. Defendants are estopped from relying on any statutes of limitation or repose by virtue of their acts of fraudulent concealment, through affirmative misrepresentations and omissions to Edward Porras and defects associated with Ranitidine-Containing Drugs including the severity, duration, and frequency of risks and complications. Defendants affirmatively withheld and/or misrepresented facts concerning the safety of Ranitidine-Containing Drugs. As a result of Defendants' misrepresentations and concealment, Edward Porras could not have known or have learned through reasonable diligence that Edward Porras had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and/or omissions of the Defendants.

188. Given Defendants' affirmative actions of concealment by failing to disclose this known but non-public information about the defects – information over which the Defendants had exclusive control – and because Edward Porras could not reasonably have known that Ranitidine-Containing Drugs were and are defective, Defendants are estopped from relying on any statutes of limitations or repose that might otherwise be applicable to the claims asserted herein.

///

///

///

1 **CAUSES OF ACTION**

2 **FIRST CAUSE OF ACTION**

3 **STRICT PRODUCTS LIABILITY – FAILURE TO WARN**
4 **(Against All Defendants)**

5 189. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if
6 fully stated herein.

7 190. At all relevant times, Defendants engaged in the business of researching, testing,
8 developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing,
9 distributing, and promoting Ranitidine-Containing Drugs, which are defective and unreasonably
10 dangerous to consumers, including Edward Porras, because they do not contain adequate warnings or
11 instructions concerning the dangerous characteristics of Ranitidine-Containing Drugs and NDMA. These
12 actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants
13 registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Drugs and
14 aimed at a consumer market.

15 191. Defendants researched, tested, developed, designed, manufactured, labeled, marketed,
16 sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of
17 commerce their Ranitidine-Containing Drugs, and in the course of same, directly advertised or marketed
18 the products to consumers and end users, including Edward Porras, and therefore had a duty to warn of
19 the risks associated with the use of Ranitidine-Containing Drugs.

20 192. At all relevant times, Defendants had a duty to properly test, develop, design,
21 manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply,
22 provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Drugs
23 did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a
24 continuing duty to warn Edward Porras of dangers associated with Ranitidine-Containing Drugs.
25 Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the
26 knowledge of an expert in the field.

27 193. Defendants had a continuing duty to provide appropriate and accurate instructions
28 regarding the proper storage and handling of Ranitidine-Containing Drugs.

1 194. At the time of manufacture, Defendants could have provided the warnings or instructions
2 regarding the full and complete risks of Ranitidine-Containing Drugs because they knew or should have
3 known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

4 195. At all relevant times, Defendants failed and deliberately refused to investigate, study, test,
5 or promote the safety or to minimize the dangers to users and consumers of their product and to those
6 who would foreseeably use or be harmed by Defendants' Ranitidine-Containing Drugs.

7 196. Even though Defendants knew or should have known that Ranitidine-Containing Drugs
8 posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks
9 associated with use and exposure to the drugs. The dangerous propensities of their products and the
10 carcinogenic characteristics of NDMA as produced within the human body as a result of ingesting
11 Ranitidine-Containing Drugs, as described above, were known to Defendants, or scientifically knowable
12 to Defendants through appropriate research and testing by known methods, at the time they distributed,
13 supplied, or sold the product, and were not known to end users and consumers, such as Edward Porras

14 197. Defendants knew or should have known that their products created significant risks of
15 serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn or instruct
16 consumers, *i.e.*, the reasonably foreseeable users, of the risks of exposure to their products. Defendants
17 failed to warn and have wrongfully concealed information concerning the dangerous level of NDMA in
18 their Ranitidine-Containing Drugs and the potential for ingested Ranitidine-Containing Drugs to
19 transform into the carcinogenic NDMA compound, and further, have made false and/or misleading
20 statements concerning the safety of Ranitidine-Containing Drugs.

21 198. At all relevant times, Defendants' Ranitidine-Containing Drugs reached the intended
22 consumers, handlers, and users or other persons coming into contact with these products, including
23 Edward Porras, without substantial change in their condition as designed, manufactured, sold,
24 distributed, labeled, and marketed by Defendants.

25 199. Edward Porras was exposed to Defendants' Ranitidine-Containing Drugs without
26 knowledge of their dangerous characteristics.

27 200. At all relevant times, Edward Porras used and/or was exposed to the use of Defendants'
28 Ranitidine-Containing Drugs while using them for their intended or reasonably foreseeable purposes,

1 without knowledge of their dangerous characteristics.

2 201. Edward Porras could not have reasonably discovered the defects and risks associated with
3 Ranitidine-Containing Drugs prior to or at the time of Edward Porras consuming Zantac. Edward Porras
4 relied upon the skill, superior knowledge, and judgment of Defendants to know about and disclose
5 serious health risks associated with using Defendants' products.

6 202. Defendants knew or should have known that the minimal warnings disseminated with
7 their Ranitidine-Containing Drugs were inadequate, failed to communicate adequate information on the
8 dangers and safe use/exposure, and failed to communicate warnings and instructions that were
9 appropriate and adequate to render the products safe for their ordinary, intended and reasonably
10 foreseeable uses.

11 203. The information that Defendants did provide or communicate failed to contain relevant
12 warnings, hazards, and precautions that would have enabled consumers such as Edward Porras to avoid
13 using the drug. Instead, Defendants disseminated information that was inaccurate, false, and misleading,
14 and which failed to communicate accurately or adequately the comparative severity, duration, and extent
15 of the risk of injuries with use of and/or exposure to Ranitidine-Containing Drugs; continued to
16 aggressively promote the efficacy of their products, even after they knew or should have known of the
17 unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through
18 aggressive marketing and promotion, any information or research about the risks and dangers of
19 ingesting Ranitidine-Containing Drugs.

20 204. This alleged failure to warn is not limited to the information contained on Ranitidine-
21 Containing Drugs' labeling. The Defendants were able, in accord with federal law, to comply with
22 relevant state law by disclosing the known risks associated with Ranitidine-Containing Drugs through
23 other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or
24 public information sources. But the Defendants did not disclose these known risks through any medium.

25 205. Had Defendants provided adequate warnings and instructions and properly disclosed and
26 disseminated the risks associated with their Ranitidine-Containing Drugs, Edward Porras could have
27 avoided the risk of developing injuries and could have obtained or used alternative medication. However,
28 as a result of Defendants' concealment of the dangers posed by their Ranitidine-Containing Drugs,

1 Edward Porras could not have averted his injuries.

2 206. Defendants' conduct, as described above, was reckless. Defendants risked the lives of
3 consumers and users of their products, including Edward Porras, with knowledge of the safety problems
4 associated with Ranitidine-Containing Drugs, and suppressed this knowledge from the general public.
5 Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public.
6 Defendants' reckless conduct warrants an award of punitive damages.

7 207. The Defendants' lack of adequate warnings and instructions accompanying their
8 Ranitidine-Containing Drugs were a substantial factor in causing Edward Porras's injuries.

9 208. As a direct and proximate result of the Defendants' failure to provide an adequate warning
10 of the risks of Ranitidine-Containing Drugs, Edward Porras suffered fatal injuries.

11 209. **WHEREFORE**, Plaintiff respectfully request this Court to enter judgment in Plaintiff's
12 favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and
13 further relief as this Court deems just and proper.

14 **SECOND CAUSE OF ACTION**

15 **STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**
16 **(Against All Defendants)**

17 210. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if
18 fully stated herein.

19 211. At all times herein mentioned, Defendants designed, manufactured, tested, marketed,
20 sold, handled, distributed, and stored the Ranitidine-Containing Drugs ingested by Edward Porras to
21 patients and physicians.

22 212. At all relevant times, the medication ingested by Edward Porras were expected to and did
23 reach Edward Porras without a substantial change in its condition as manufactured, handled, distributed,
24 stored, and sold by Defendants.

25 213. At all relevant times, the medications ingested by Edward Porras were used in a manner
26 that was foreseeable and intended by Defendants.

27 214. The Ranitidine-Containing Drugs ingested by Edward Porras were not reasonably safe
28 for their intended use and were defective with respect to their manufacture, as described herein, in that

1 Defendants deviated materially from their design, manufacturing, handling, and storage specifications
2 and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Edward
3 Porras

4 215. The Defendants' Ranitidine-Containing Drugs are inherently dangerous and defective,
5 unfit and unsafe for its intended and reasonably foreseeable uses, and do not meet or perform to the
6 expectations of patients and their health care providers.

7 216. The Ranitidine-Containing Drugs create risks to the health and safety of the patients that
8 are far more significant and devastating than the risks posed by other products and treatments available
9 to treat the corresponding medical conditions, and which far outweigh the utility of the ranitidine-
10 containing products because of Defendants' manufacturing defects, which included but were not limited
11 to:

- 12 a. Failure to follow Good Manufacturing Practices;
- 13 b. Failure to adequately inspect/test the drugs during the manufacturing process;
- 14 c. Failure to implement procedures that would reduce or eliminate NDMA levels in
15 Ranitidine-Containing Drugs;
- 16 d. Failure to implement appropriate handling instructions and storage conditions for the
17 drug.

18 217. Defendants have intentionally and recklessly manufactured the Ranitidine-Containing
19 Drugs with wanton and willful disregard for the rights and health of Edward Porras, and with malice,
20 placing their economic interests above the health and safety of Edward Porras

21 218. The manufacturing defects in Defendants' Ranitidine-Containing Drugs were substantial
22 factors in causing Edward Porras's injuries

23 219. As a direct and proximate result of the Defendants' improper manufacturing of
24 Ranitidine-Containing Drugs, Edward Porras suffered fatal injuries.

25 **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor
26 for damages, together with interest, costs herein incurred, attorneys' fees and all such other and further
27 relief as this Court deems just and proper.

28 ///

THIRD CAUSE OF ACTION
NEGLIGENCE – FAILURE TO WARN
(Against All Defendants)

220. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

221. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Drugs. Defendants knew or by the exercise of reasonable care should have known that their Ranitidine-Containing Drugs are not accompanied with adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Drugs and NDMA. These actions were under the ultimate control and supervision of Defendants.

222. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, handled, stored, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce their Ranitidine-Containing Drugs, and in the course of same, directly advertised or marketed the products to consumers and end users, including Edward Porras, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Drugs.

223. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Drugs did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Edward Porras of dangers associated with Ranitidine-Containing Drugs. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

224. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper storage and handling of Ranitidine-Containing Drugs.

225. At the time of manufacture, Defendants could have provided warnings or instructions regarding the full and complete risks of Ranitidine-Containing Drugs because they knew or should have known use of Ranitidine-Containing Drugs was dangerous, harmful and injurious when used by Edward

1 Porras in a reasonably foreseeable manner.

2 226. At all relevant times, Defendants failed and deliberately refused to investigate, study, test,
3 or promote the safety or to minimize the dangers to users and consumers of their product and to those
4 who would foreseeably use or be harmed by Defendants' Ranitidine-Containing Drugs.

5 227. Defendants knew or should have known that Ranitidine-Containing Drugs posed a grave
6 risk of harm, but failed to exercise reasonable care to warn of the dangerous risks associated with use
7 and exposure to the products. The dangerous propensities of their products and the carcinogenic
8 characteristics of NDMA as produced within the human body as a result of ingesting Ranitidine-
9 Containing Drugs, as described above, were known to Defendants, or scientifically knowable to
10 Defendants through appropriate research and testing by known methods, at the time they distributed,
11 supplied or sold the product, and were not known to end users and consumers, such as Edward Porras

12 228. Defendants further breached their duty by failing to use reasonable care to adequately
13 warn or instruct consumers (*i.e.*, the reasonably foreseeable users) of the risks of exposure to their
14 products. Defendants failed to warn and have wrongfully concealed information concerning the
15 dangerous level of NDMA in their Ranitidine-Containing Drugs and the potential for ingested
16 Ranitidine-Containing Drugs to transform into the carcinogenic NDMA compound, and further, have
17 made false and/or misleading statements concerning the safety of Ranitidine-Containing Drugs.

18 229. At all relevant times, Edward Porras used and/or was exposed to excessive levels of
19 NDMA through the use of Defendants' Ranitidine-Containing Drugs while using them for their intended
20 or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

21 230. Defendants knew or should have known that the minimal warnings disseminated with
22 their Ranitidine-Containing Drugs were inadequate, failed to communicate adequate information on the
23 dangers and safe use/exposure, and failed to communicate warnings and instructions that were
24 appropriate and adequate to render the products safe for their ordinary, intended and reasonably
25 foreseeable uses.

26 231. The information that Defendants did provide or communicate failed to contain relevant
27 warnings, hazards, and precautions that would have enabled consumers such as Edward Porras to avoid
28 using the product. Instead, Defendants disseminated information that was inaccurate, false, and

misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to Ranitidine-Containing Drugs; continued to aggressively promote the efficacy of their products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Drugs.

232. A reasonable company under the same or similar circumstance would have warned and instructed of the dangers of Ranitidine-Containing Drugs.

233. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Drugs' labeling. The Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Drugs through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But the Defendants did not disclose these known risks through any medium.

234. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Drugs, Edward Porras could have avoided the risk of developing injuries and could have obtained or used alternative medication. However, as a result of Defendants' concealment of the dangers posed by their Ranitidine-Containing Drugs, Edward Porras could not have averted his injuries.

235. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Edward Porras, with knowledge of the safety problems associated with Ranitidine-Containing Drugs, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

236. The Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Drugs were a substantial factor in causing Edward Porras's injuries.

237. As a direct and proximate result of the Defendants' failure to provide an adequate warning of the risks of Ranitidine-Containing Drugs, Edward Porras suffered fatal injuries.

238. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's

1 favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and
2 further relief as this Court deems just and proper.

3 **FOURTH CAUSE OF ACTION**
4 **NEGLIGENT PRODUCT DESIGN**
5 **(Against All Defendants)**

6 239. The Defendants knew or, by the exercise of reasonable care, should have known, ordinary
7 consumers such as Edward Porras would not have realized the potential risks and dangers of Ranitidine-
8 Containing Drugs.

9 240. The Defendants owed a duty to all reasonably foreseeable users to design a safe product.

10 241. The Defendants breached their duty by failing to use reasonable care in the design of
11 Ranitidine-Containing Drugs because the drug exposed users to unsafe levels of the carcinogen NDMA.

12 242. The Defendants breached their duty by failing to use reasonable care in the design of
13 Ranitidine-Containing Drugs by negligently designing the drug with an inherent susceptibility to form
14 NDMA.

15 243. The Defendants breached their duty by failing to use reasonable care in the design of
16 Ranitidine-Containing Drugs by negligently designing in design and formulation, in one or more of the
17 following ways:

- 18 a. When placed in the stream of commerce, Defendants' Ranitidine-Containing Drugs were
19 defective in design and formulation, and, consequently, dangerous to an extent beyond
20 that which an ordinary consumer would contemplate;
- 21 b. When placed in the stream of commerce, Defendants' Ranitidine-Containing Drugs were
22 unreasonably dangerous in that they were hazardous and posed a grave risk of cancer and
23 other serious illnesses when used in a reasonably anticipated manner;
- 24 c. When placed in the stream of commerce, Defendants' Ranitidine-Containing Drugs
25 contained unreasonably dangerous design defects and were not reasonably safe when
26 used in a reasonably anticipated or intended manner;
- 27 d. Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing
28 Drugs and, specifically, the ability for Ranitidine-Containing Drugs to transform into the

1 carcinogenic compound NDMA within the human body;

- 2 e. Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing
3 Drugs and, specifically, the ability for Ranitidine-Containing Drugs to develop increasing
4 levels of NDMA over time under anticipated and expected storage and handling
5 conditions;
- 6 f. Exposure to Ranitidine-Containing Drugs presents a risk of harmful side effects that
7 outweigh any potential utility stemming from the use of the drug;
- 8 g. Defendants knew or should have known at the time of marketing Ranitidine-Containing
9 Drugs that exposure to Ranitidine-Containing Drugs could result in cancer and other
10 severe illnesses and injuries;
- 11 h. Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-
12 Containing Drugs; and
- 13 i. Defendants could have employed safer alternative designs and formulations. For
14 example, the Defendants could have added ascorbic acid (Vitamin C) to each dose of
15 Ranitidine-Containing Drugs, which is known to scavenge nitrites and reduce the ability
16 of the body to recombine ranitidine into NDMA.

17 244. The Defendants breached their duty by failing to use reasonable care by failing to use
18 cost effective, reasonably feasible alternative designs. there was a practical, technically feasible, and
19 safer alternative design that would have prevented the harm without substantially impairing the
20 reasonably anticipated or intended function of Defendants' Ranitidine-Containing Drugs.

21 245. A reasonable company under the same or similar circumstances would have designed a
22 safer product.

23 246. Edward Porras was harmed directly and proximately by the Defendants' failure to use
24 reasonable care in the design of their Ranitidine-Containing Drugs. Such harm includes significant
25 exposure to a known carcinogen, NDMA, which can cause or contribute the development of cancers.

26 247. Defendants' defective design of Ranitidine-Containing Drugs was willful, wanton,
27 malicious, and conducted with reckless disregard for the health and safety of users of the Ranitidine-
28 Containing Drugs, including Edward Porras

248. The defects in Defendants' Ranitidine-Containing Drugs were substantial factors in causing Edward Porras's injuries.

249. As a direct and proximate result of the Defendants' improper manufacturing of Ranitidine-Containing Drugs, Edward Porras suffered fatal injuries.

250. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

FIFTH CAUSE OF ACTION
NEGLIGENT MANUFACTURING
(Against All Defendants)

251. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

252. At all relevant times, the Defendants manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Drugs that Edward Porras consumed.

253. The Defendants had a duty to exercise reasonable care, in the manufacturing, testing, marketing, sale, handling, storing, packaging, and distribution of Ranitidine-Containing Drugs.

254. The Defendants knew or, by the exercise of reasonable care, should have known, use of Ranitidine-Containing Drugs were carelessly manufactured, packaged was dangerous, harmful and injurious when used by Edward Porras in a reasonably foreseeable manner.

255. The Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Edward Porras would not have realized the potential risks and dangers of Ranitidine-Containing Drugs improperly manufactured, tested, marketed, sold, handled, distributed, and stored.

256. Without limitation, examples of the manner in which Defendants breached their duty to exercise reasonable care in manufacturing Ranitidine-Containing Drugs, included:

- a. Failure to follow Good Manufacturing Practices;
- b. Failure to adequately inspect/test the drugs during the manufacturing process;
- c. Failure to implement procedures that would reduce or eliminate NDMA

1 levels in Ranitidine-Containing Drugs; and

2 d. Failure to implement appropriate handling instructions and storage
3 conditions for the drug.

4 257. A reasonable manufacturer under the same or similar circumstances would have
5 implemented appropriate manufacturing procedures to better ensure the quality and safety of their
6 product.

7 258. Edward Porras was harmed directly and proximately by the Defendants' failure to use
8 reasonable care in the manufacture of their Ranitidine-Containing Drugs. Such harm includes significant
9 exposure to a known carcinogen, NDMA, which can cause or contribute the development of cancers.

10 259. Defendants' improper manufacturing of Ranitidine-Containing Drugs was willful,
11 wanton, malicious, and conducted with reckless disregard for the health and safety of users of the
12 Ranitidine-Containing Drugs, including Edward Porras

13 260. The defects in Defendants' Ranitidine-Containing Drugs were substantial factors in
14 causing Edward Porras's injuries.

15 261. As a direct and proximate result of the Defendants' improper manufacturing of
16 Ranitidine-Containing Drugs, Edward Porras suffered fatal injuries.

17 262. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's
18 favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and
19 further relief as this Court deems just and proper.

20 **SIXTH CAUSE OF ACTION**

21 **NEGLIGENT MISREPRESENTATION**
22 **(Against All Defendants)**

23 263. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if
24 fully stated herein.

25 264. At all relevant times, Defendants designed, manufactured, tested (or not), packaged,
26 labeled, marketed, advertised, promoted, supplied, stored, handled, warehoused, distributed, sold and/or
27 otherwise placed Ranitidine Containing Drugs into the stream of commerce, and therefore owed a duty
28 of reasonable care to avoid causing harm to those that consumed Ranitidine-Containing Drugs, such as

1 Edward Porras

2 265. Defendants were negligent, reckless, and careless and owed a duty to Edward Porras to
3 make accurate and truthful representations regarding Ranitidine Containing Drugs, Defendants breached
4 their duty, thereby causing Edward Porras to suffer harm.

5 266. Defendants represented to Edward Porras via the media, advertising, website, social
6 media, packaging, and promotions, among other misrepresentations described herein that:

7 267. Ranitidine-Containing Drugs were both safe and effective for the lifetime of the product,
8 when in fact, the drug contains unsafe levels of NDMA far in excess of the 96 ng limit that increases as
9 the product ages;

10 268. Consumption of Ranitidine-Containing Drugs would not result in excessive amounts of
11 NDMA being formed in their bodies; and

12 269. The levels of NDMA in Ranitidine-Containing Drugs have no practical clinical
13 significance; and

14 270. Ranitidine-Containing Drugs were safe for their intended use when, in fact, Defendants
15 knew or should have known the products were not safe for their intended purpose.

16 271. These representations were false. Because of the unsafe levels of NDMA in Ranitidine-
17 Containing Drugs, the drug presented an unacceptable risk of causing cancer. Ranitidine-Containing
18 Drugs are so unsafe that the FDA was compelled to order the immediate ban of all Ranitidine-Containing
19 Drugs on April 1, 2020.

20 272. Defendants knew or should have known these representations were false and negligently
21 made them without regard for their truth.

22 273. Defendants had a duty to accurately provide this information to Edward Porras In
23 concealing this information from Edward Porras, Defendants breached their duty. Defendants also
24 gained financially from, and as a result of their breach.

25 274. Defendants intended for Edward Porras to rely on these representations.

26 275. Each of these misrepresentations were material at the time they were made. In particular,
27 each of the misrepresentations concerned material facts that were essential to the analysis undertaken by
28 Edward Porras as to whether to purchase or consume Ranitidine Containing Drugs.

276. Defendants have yet to correct these misrepresentations about Ranitidine-Containing Drugs.

277. Edward Porras reasonably relied on these representations and were harmed as described herein. Edward Porras's reliance on Defendants' representation was a substantial factor in causing Edward Porras's harms. Had Defendants told Edward Porras the truth about the safety and composition of Ranitidine-Containing Drugs, Edward Porras would not have consumed or purchased them.

278. Defendants' acts and omissions as described herein were committed in reckless disregard of Edward Porras's rights, interests, and well-being to enrich Defendants.

279. Edward Porras was injured as a direct and proximate result of Defendants' negligent misrepresentations regarding Ranitidine-Containing Drugs as described herein.

280. **WHEREFORE**, Plaintiff respectfully request this Court to enter judgment in Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

SEVENTH CAUSE OF ACTION

WRONGFUL DEATH
(Against All Defendants)

281. Plaintiffs incorporate by reference every allegation set forth in preceding paragraphs as if fully stated herein.

282. Survival and Wrongful Death Plaintiffs are the surviving heirs, successors in interest, and/or personal representatives of Decedents, as identified above, who used Ranitidine-Containing Drugs and were injured and died as a result.

283. The injuries and damages of Plaintiff and Decedent were caused by the wrongful acts, omissions, and fraudulent misrepresentations of Defendants.

284. As a result of the conduct of Defendants and Edward Porras's use of Ranitidine-Containing Products, Edward Porras suffered fatal injuries.

285. As a result of the death of Edward Porras, Plaintiff was deprived of love, companionship, comfort, support, affection, society, solace, and support of Edward Porras

286. Plaintiff is entitled to recover economic and non-economic damages against all

1 Defendants for wrongful death directly and legally caused by the defects in Ranitidine-Containing Drugs
2 and the negligent conduct, acts, errors, omissions, and intentional and negligent misrepresentations of
3 Defendants, and each of them.

4 **EIGHTH CAUSE OF ACTION**

5 **SURVIVAL ACTION**
6 **(Against All Defendants)**

7 287. Plaintiffs incorporate by reference every allegation set forth in preceding paragraphs as
8 if fully stated herein.

9 288. Edward Porras incurred special damages in the form of the reasonable value of services
10 rendered for medical care for the injuries that Edward Porras sustained prior to death, all caused by
11 Edward Porras's exposure to Ranitidine-Containing Products. Survival and Wrongful Death Plaintiffs
12 are the heirs, personal representatives, and/or successors in interest and are authorized to bring this
13 survival action on behalf of Edward Porras's Estate pursuant to Code of Civil Procedure § 377.31, et
14 seq.

15 289. Plaintiff incurred special damages for losses sustained by Edward Porras in the form of
16 the reasonable value of services rendered for medical care for the injuries sustained by Edward Porras
17 prior to death, lost earnings, and other special damages.

18 290. As a direct and proximate result of consuming Ranitidine-Containing Drugs and the
19 conduct of Defendants, Plaintiff and Edward Porras sustained the damages as set forth above.

20 **JURY TRIAL DEMAND**

21 291. Plaintiff demands a trial by jury on all the triable issues within this pleading.

22 **PRAYER FOR RELIEF**

23 292. WHEREFORE, Plaintiff requests the Court to enter judgment in Plaintiff's favor and
24 against the Defendants for:

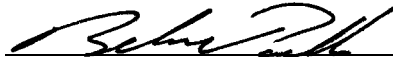
25 a. actual or compensatory damages in such amount to be determined at trial
26 and as provided by applicable law;

27 b. exemplary and punitive damages sufficient to punish and deter the
28 Defendants and others from future wrongful practices;

- 1 c. pre-judgment and post-judgment interest;
2 d. costs including reasonable attorneys' fees, court costs, and other litigation
3 expenses; and
4 e. any other relief the Court may deem just and proper.

5 Dated: December 14, 2022.

6 **DALIMONTE RUEB STOLLER, LLP**

7
8 

9 BEHRAM V. PAREKH, SBN 180361

10 *behram.parekh@drlawllp.com*

11 GREGORY RUEB, Esq. SBN 154589

12 *greg@drlawllp.com*

13 DALIMONTE RUEB STOLLER LLP

14 515 S. Figueroa St. Ste 1550

15 Los Angeles, CA 90071

16 T: (925) 457-8415

17 T: 619.821.2305

18 F: 855.203.2035

19 *Attorneys for Plaintiffs*